UNITED STATES DEPARTMENT OF AGRICULTURE BEFORE THE SECRETARY OF AGRICULTURE

In re:	} } }	FMIA Docket No. 15-0096
Rio Tex Wholesale Meat Processing Division	} } }	
A No. 1 Company of the Company of th	} } }	
Respondents	} } } }	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. and 9 C.F.R. § 500.1 et seq.) to withdraw federal inspection services from Respondents. This proceeding was commenced by a Complaint filed on April 7, 2015, by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA) which is responsible for administration of Federal inspection services for both meat and poultry. This decision is entered pursuant to the consent decision provisions of the rules of practice applicable to this proceeding (7 C.F.R. § 1.138).

Respondents admit the findings of fact, as set forth herein, and specifically admit that the Secretary has jurisdiction in this matter. Respondents neither admit nor deny the remaining allegations and waive oral hearing and further procedure. Respondents and its owners, officers, directors, partners, successors, assigns, and affiliates waive any claim against the Complainant under the Equal Access to Justice Act of 1980 (5 U.S.C. section 504 et seq.) and waives any

other action against USDA or its employees in connection with this proceeding and the facts and events that gave rise to the proceeding. The Respondents consent and agree, for the purpose of settling this proceeding and for such purpose only, to the entry of this decision.

The Respondents agree to the entry of this decision.

Findings of Fact

- 1. Rio Tex Wholesale Meat Processing Division is now, and was at all times material herein, a business operating a meat and poultry processing facility at 1140 W. Second Street, Mercedes, Texas, 78570.
- 2. Rio Tex Wholesale Meat Processing Division is now, and was at all times material herein, a recipient of Federal inspection services at its place of business in Mercedes, Texas, and designated as official Establishment Number 13545.
- 3. On April 1, 2014, and August 25, 2014, FSIS issued Notices of Suspension whereby FSIS withheld marks of inspection and suspended the assignment of inspectors at the facility. Each of these suspensions was based upon Respondents failure to comply with 9 C.F.R. 416, 417 and/or 430. Based upon proffered corrective actions and written assurances, each of the suspensions listed in this paragraph was held in abeyance pending verification by FSIS personnel that the corrective actions and preventive measures were effectively implemented.
- 4. On February 24, 2015, Intensified Verification Testing sampling was performed by FSIS personnel. On March 2, 2015, results of the analysis of the samples collected were reported by the laboratory and included seven (7) *Lm* positive findings on a product contact surfaces, and five product samples. Based on these positive findings, on March 2, 2015, FSIS reinstated the Notice of Suspension for ready-to-eat (RTE) operations.

Conclusion

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

Order

Federal meat and poultry inspection services under Title I of the FMIA are withdrawn from Respondent owners, officers, directors, partners, affiliates, successors and assigns, directly or through any business or other device, for a period of three (3) years beginning on the effective date of this Order; Provided, however, said withdrawal of inspection services shall be held in abeyance, and conditional Federal meat inspection services shall be provided to Respondent for so long as the conditions set forth herein below, in addition to all other statutory and regulatory requirements for applicable inspection services, are met:

- 1. Prior to the resumption of Federal inspection service, 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 416, 417, and 430, 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, *Listeria monocytogenes (Lm)* sampling and testing program, and other written sanitation, process controls, and sampling or testing programs required by regulation or this Order and
 - (b) the physical and sanitary conditions of the Respondent's establishment.
- 2. During the period of this Order, within its discretion, FSIS may conduct examinations of records, Intensified Verification Testing (IVT), and other verification and monitoring activities to ensure Respondent's compliance, implementation, and the effectiveness of its SPS,

SSOP, HACCP, *Lm* sampling and testing program and other systems, plans, and records required by the FMIA, the regulations, and this Order.

Sanitation Performance Standards (SPS)

- 3. Prior to the resumption of Federal inspection services, and subject to verification by FSIS, Respondent shall develop written procedures, including monitoring, corrective action, and recordkeeping procedures that Respondent will implement to operate and maintain its establishment, including its premises, facilities, equipment, and outside premises, in a manner sufficient to prevent the creation of insanitary conditions and practices, comply with the requirements of the Sanitation Performance Standard (SPS) regulations (9 C.F.R. 416.1 to 416.6), and ensure that meat and poultry food products prepared, stored, and packaged are not adulterated.
- 4. Upon the resumption of Federal inspection services, and subject to verification by FSIS, the Respondent shall:
- (a) 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, comply with the requirements of the SPS regulations, and ensure that meat and poultry food products are not adulterated; and
- (b) 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.

Sanitation Standard Operating Procedures (SSOP)

- 5. Prior to the resumption of Federal 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 this Order and regulatory requirements, 9 C.F.R. 416.11 to 416.16, to ensure sanitary conditions and prevent product adulteration; and
- (b) address specific procedures within the written SSOP, including the following: (i) cleaning and sanitizing equipment and utensils; (ii) written instructions for complex equipment use and methods of cleaning; (iii) proper handling, storage, denaturing, and disposal of inedible products; (iv) re-conditioning of contaminated product; (v) employee hygienic practices; and (vi) employee traffic.
- 6. Upon the resumption of Federal inspection services, and subject to verification by FSIS, Respondent shall:
- (a) implement and maintain, on a daily and ongoing basis, its SSOP system as provided in this Order and regulatory requirements of 9 C.F.R. 416 to ensure sanitary conditions and prevent product adulteration; and
- (b) implement corrective and preventive actions as required by 9 C.F.R. § 416.15, 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, and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Points (HACCP) System

- 7. Prior to the resumption of Federal inspection services, and subject to verification by FSIS, Respondent shall:
- (a) reassess its HACCP system to describe each system of process controls and procedures that Respondent will implement and utilize on a daily and ongoing basis to control and prevent the introduction of food safety hazards in their meat and poultry products. These plans shall address specific process controls and procedures with Respondent's HACCP system(s) 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 *Lm* as a hazard reasonably likely to occur because it has historically occurred in the establishment; and (iii) measures to eliminate or reduce and control the level of *Lm* to prevent contamination of Respondent finished Ready-to-Eat (RTE) meat and poultry food products, food contact surfaces, and non-contact environmental surfaces;
- (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).
- 8. Upon resumption of Federal inspection services, and subject to the verification of FSIS, Respondent shall:
- (a) implement, and maintain on a daily and ongoing basis the HACCP system(s) and plan(s), in accordance with the requirements of 9 C.F.R. Part 417 and the requirements of this Order;

- (b) conduct initial in-plant validation during the first ninety (90) days of operations, in accordance with 9 C.F.R. Part 417.4(a)(1);
- (c) implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP system(s) and plan(s) 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 assessment, validation, and testing of the adequacy of the critical control points, critical limits, monitoring, and recordkeeping procedures, and corrective actions set forth in the HACCP system(s) and plan(s), to ensure Respondent's food safety system remains validated over time, as required by 9 C.F.R. Part 417.

Listeria monocytogenes Sampling and Testing Program

- 9. Prior to the resumption of Federal inspection services, and subject to verification by FSIS, the Respondent shall develop a written *Lm* sampling and testing program for its RTE products in accordance with 9 C.F.R. Part 430 and, at a minimum, shall include:
 - (a) initial start-up production sampling and testing;
 - (b) routine production sampling and testing;
 - (c) intensified production sampling and testing performed in response to positive analysis results;
 - (d) alternative 1 for the production of post-lethality exposed RTE products;
 - (e) testing for product, food contact surfaces, indirect contact surfaces, and environmental/non-food contact surfaces;
 - (f) procedures to notify FSIS of all testing and sampling results, including presumptive

positives, immediately upon receipt of sample results; and

(g) designation in writing, subject to the concurrence of FSIS, one full time person and one alternate who shall be responsible for conducting sampling or other activities under Respondent's written *Lm* program and 9 C.F.R. Part 430.

Initial Start-up Production Sampling and Testing

- 10. Upon resumption of Federal inspection services, and subject to verification by FSIS, the Respondent shall implement a ten (10) consecutive production days initial start-up production period intensified sampling and testing production schedule, to include:
- (a) full establishment operations including production of RTE meat and poultry products;
- (b) intensified testing for product, food contact surfaces, indirect contact surfaces, and non-food contact surfaces during the full ten (10) consecutive production days initial start-up production period to ensure no positive *Lm* findings;
- (c) the implementation of hold and test procedures for all RTE meat and poultry products produced until all laboratory results are received for ten (10) consecutive production days;
- (d) testing and sampling for *Lm* at the following frequency with the majority of samples collected three (3) hours after production starts: (i) For environmental/non-food contact surfaces/indirect non-food contact surfaces, random samples in any area where RTE product is processed, stored, or held, and any facility site(s) that had previously tested positive, including random sampling and testing for five (5) sites from each production line for a total of ten (10) 5 sites per regular eight (8) hours production day; in addition random sampling and testing for five (5) sites included in the establishment's Listeria Program; (ii) For food contact surfaces in any

area where RTE product is exposed to the environment and food contact surfaces that can only be sampled prior to or after production ends, random sampling and testing for ten (10) sites from each production line per regular eight (8) hours production day; (iii) For product samples, nine (9) samples of final packaged product consisting of three (3) random samples taken at three (3) random times from each production line per regular eight (8) hours production day starting at least two (2) to three (3) hours into the start of production; and

- (e) Holding procedures for all products produced during the full ten (10) consecutive production days initial start-up production period until all laboratory results are received for all ten (10) consecutive production days, and information regarding all testing has been provided to FSIS for review, verification, and concurrence.
- 11. Respondent may in the event of the successful completion of the initial start-up period for all ten (10) consecutive days of production: (i) ship all RTE products produced during those ten (10) consecutive production days initial start-up production; and (ii) continue operations, testing, and sampling for *Lm* under its routine production sampling program as provided in paragraph 15 of this Order.
- 12. In the event of any positive *Lm* test result for product or food contact surfaces at any time during the ten (10) consecutive production day initial start-up period Respondent shall immediately:
 - (a) Suspend operations;
- (b) Destroy all products produced and held during the full ten (10) production days initial start-up period; take necessary corrective and preventive measures to address the *Lm* positive finding(s);
 - (c) reevaluate its Lm, SSOP, HACCP, and other programs or plans to determine if

modifications need to be made to address preventive and corrective measures;

- (d) document appropriate corrective and preventive actions;
- (e) retrain employees in the *Lm* program or other programs or procedures if in the Respondent's reassessment, it is determined that the contamination was due to employee practices or actions and document all employee training; and
- (f) submit the Respondent's proposed corrective actions, preventive measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program, or other systems, programs, or plans to FSIS for review, verification, and concurrence prior to resumption of operations.
- 13. In the event of any positive *Lm* test results for environmental/non-food contact/indirect non-food contact surface samples in any area where RTE product is processed, stored or held, and any facility site(s) that had previously tested positive, the Respondent shall:
- (a) submit its proposed corrective actions, preventive measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program, or other systems, programs or plans to FSIS for review, verification, and concurrence; and
- (b) continue to hold all products produced until the successful completion of the entire initial start-up period, all laboratory results are received and all information regarding all testing has been provided to FSIS for review, verification, and concurrence. FSIS will then make a determination concerning the disposition of the product based upon the information provided by the Respondent regarding the sanitary conditions of the facility and the wholesomeness of the product.
 - 14. Respondent shall, in the event of any positive Lm test results as described in

paragraph 12 of this Order re-start its ten (10) consecutive production day initial start-up production period intensified sampling and testing program as provided in paragraph 10 of this Order until all laboratory results are received for all ten (10) consecutive production days.

Routine Production Sampling and Testing

- 15. The Respondent's routine production sampling and testing shall, at a minimum, include:
- (a) testing and sampling frequency as follows: (i) Environmental/non-food contact surface/indirect non-food contact surface samples in any area where RTE product is processed, stored, or held, and any facility site(s) that had previously tested positive, random sampling and testing for five (5) sites from each production line on a daily basis to be taken at least three (3) hours into production, in addition random sampling and testing of five (5) sites from the other areas included in the establishment's Listeria program for a total of ten (10) samples; (ii) For food contact surfaces in any area where RTE product is exposed to the environment and food contact sites that can only be sampled prior to or after production ends, random sampling and testing for seven (7) sites from each production line per regular eight (8) hours production day; and (iii) For Product Samples, five (5) samples of final packaged product consisting of five (5) random samples taken at three (3) random times from each production line per regular eight (8) hours production day starting at least two (2) to three (3) hours into the start of production; and
 - (b) the size and location of the sites that will be sampled;
- (c) an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm*, or indicator organism, is maintained; random testing and sampling for all facility sites and production days that will give an equal opportunity of selection for all sites and times;

- (d) hold and test procedures for all products produced until negative results for food contact surfaces and product are received; and
 - (e) testing for Lm for product samples.
- 16. In the event of any positive *Lm* test result for product or food contact surfaces, the Respondent shall voluntarily and immediately suspend RTE operations, and prior to the resumption of operations:
- (a) take necessary corrective and preventive measures to address the Lm positive finding;
- (b) reevaluate its Lm, SSOP, HACCP and other programs or plans to determine if modifications need to be made to address preventive and corrective measures;
 - (c) document appropriate corrective and preventive actions;
- (d) retrain employees in the *Lm* program if in the Respondent's reassessment it is determined that the contamination was due to employee practice or actions;
 - (e) document any employee training; and
- (f) destroy product or present a written request to FSIS for product rework or reconditioning that includes a validated lethality treatment for FSIS review, verification, and concurrence;
- (g) submit proposed corrective actions, preventive measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program, or other programs or plans to FSIS for review, verification, and concurrence.
- 17. In the event of any positive *Lm* test results for environmental/non-food contact surface/indirect non-food contact surface samples in any area where RTE product is processed, stored, or held, and any facility site(s) that had previously tested positive, the Respondent shall:

- (a) submit its proposed corrective actions, preventive measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program or other programs or plans to FSIS for review, verification, and concurrence:
- (b) after implementing corrective actions, conduct three (3) consecutive re-tests of the positive site;
- (c) determine the location of the five (5) nearest food contact surface sites where RTE product is processed, stored or held and test these sites in conjunction with any testing of the positive site in (b) above; and
- (d) If any indirect or environmental/non-food contact surface re-test in (b) above or any food contact surface sites in (c) above are positive, the Respondent shall immediately implement its intensified production sampling program, as provided in paragraph 20 of this Order.
- 18. Respondent shall, in the event of any positive *Lm* test results as described in paragraph 16 and 17 of this Order, implement its intensified production sampling program, as provided in paragraph 20 of this Order.
- 19. Following the initial start-up and production sampling, Respondent shall conduct in-plant validation during the first ninety (90) days of normal RTE operations and evaluate its *Lm* routine production sampling and testing program. If modifications need to be made, Respondent shall:
- (a) Submit its proposed changes to its routine sampling and testing program including explanation of why the changes are sufficient to ensure effective control of *Lm*, or indicator organism, is maintained; and supporting documentation including sampling and testing for the last ninety (90) days of RTE operations to FSIS for review, verification, and concurrence.

Intensified Production Sampling and Testing

- 20. The Respondent's intensified production sampling and testing shall include, at a minimum:
- (a) intensified testing for product, food contact surfaces, and environmental/non-food contact surfaces for one "work week" (a "work week" shall mean all production days, Sunday through Saturday), and the implementation of hold and test procedures for all RTE products produced until all laboratory results are received to ensure no *Lm* findings;
- (b) testing and sampling frequency as follows: (i) For environmental/non-food contact surface/indirect non- food contact surface samples in any areas where RTE product is processed, stored, or held, and any facility site(s) that had previously tested positive, sampling and testing for five (5) sites from each production line on a daily basis to be taken three (3) hours into production, in addition to random sampling and testing of five (5) sites from the other areas included in the establishment's Listeria program for a total of ten (10) samples; per regular eight (8) hours production day; (ii) For food contact surfaces/ in any area where RTE product is exposed to the environment, and food contact sites that can only be sampled prior to or after production ends, random sampling and testing for ten (10) sample sites from each production line per regular eight (8) hours production day; and (iii) For product samples, nine (9) samples of final packaged product consisting of three (3) random samples taken at three (3) random times from each production line per regular eight (8) hours production day starting at least two (2) to three (3) hours into the start of production; and
- (c) random testing and sampling for all facility sites along with the selection of any facility site(s) that had previously tested positive; and
 - (d) testing for *Lm* in all areas where RTE product is processed, stored, or held.

- 21. In the event of any positive *Lm* test results for product or food contact surfaces, the Respondent shall voluntarily and immediately suspend RTE operations in all USDA production areas and end production when remaining products in process have been packaged. Prior to the resumption of operations, the Respondent shall:
 - (a) take necessary corrective and preventive measures to address the *Lm* positive finding;
- (b) reevaluate its Lm, SSOP, HACCP and other programs or plans to determine whether modifications need to be made to address preventive and corrective measures;
 - (c) document appropriate corrective and preventive actions;
- (d) retrain employees in the *Lm* program if in the Respondent's reassessment it is determined that the contamination was due to employee practices or actions;
- (e) document all employees training; destroy product or present a written request to FSIS for product rework or reconditioning with a validated lethality treatment for FSIS review, verification, and concurrence; and
- (f) submit its proposed corrective actions, preventive measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program, or other systems, programs or plans to FSIS for review, verification and concurrence.
- 22. In the event of any positive *Lm* test results for indirect contact surfaces or environmental/non-food contact surfaces, the Respondent shall:
- (a) submit its proposed corrective actions, preventive measures, and any changes to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans to FSIS for review, verification, and concurrence.
 - (b) present a written request to FSIS for the disposition of the product. FSIS will

then make a determination concerning the disposition of the product produced during the intensified testing period based upon the information provided by the Respondent regarding the sanitary conditions of the facility and the wholesomeness of the product.

- 23. The Respondent shall, in the event of any positive *Lm* test results as described in paragraphs 21 or 22 of this Order, re-start its intensified production sampling as provided in paragraph 20 of this Order until negative results are received for one workweek of production days.
- 24. The Respondent shall continue operations, testing, and sampling for *Lm* under its routine production-sampling program as provided in paragraphs 15 to 19 of this Order, upon receiving all laboratory reports verifying negative test results for all product and for food contact surfaces for one work week of production days.

Laboratory Methods

- 25. Respondent shall have all samples tested at its contract laboratory;
- 26. Respondent shall document and maintain sample laboratory results and records regarding the implementation and monitoring of its *Lm* program as provided in this Order, including corrective actions, regulatory records, and preventive measures, in accordance with 9 C.F.R. § 417.5, and make these establishment records available to FSIS personnel for review and/or copying immediately upon request.

Establishment Management and Personnel

27. Prior to the resumption of inspection services, and subject to verification by FSIS, Respondent shall designate, in writing, two full-time employees, one as a principal and the other as an alternate, who shall be responsible for the overall implementation, coordination, documentation, monitoring, recordkeeping, review and maintenance of the facility's SPS,

SSOPs, and HACCP plans, *Lm* sampling and testing programs, and all other requirements of this Order.

- (a) Prior to the resumption of inspection services, Respondent shall provide a detailed summary of the authority and responsibilities that the designated principal and alternate are granted with respect to actions taken in the establishment.
- (b) The designated principal and alternate shall have completed, within forty-five (45) calendar days of the effective date of this Order and subject to verification by FSIS, a course of instruction in the seven principles of HACCP, SSOP, and be trained in the *Lm* sampling and testing procedures, and shall be present at all times when operations requiring inspection are conducted. Respondent shall not conduct any processing operations in the absence of said designated principal and alternate. The designated principal and alternate shall have authority to hold up production, stop production, remove product from production, or take positive control of any products produced, processed, packed, or stored at the establishment that are or are believed to be adulterated or misbranded, or when facility sanitation or production deficiencies are observed. Respondent may name a new designated principal and/or alternate employee or employees upon written notification to the FSIS.

Employee Training

- 28. Prior to the resumption, and subject to the verification of FSIS, Respondent shall develop a training program for all current employees and future hires to ensure that employees are trained in all aspects of food safety measures and regulatory requirements, including the requirements of the SPS, SSOP, HACCP, *Lm*, sampling and testing, recordkeeping procedures, and Good Manufacturing Practices (GMPs), relevant to each employees position.
 - 29. Within forty-five (45) calendar days of the effective date of this Order and subject

to verification by FSIS, Respondent shall train all current employees consistent with the requirements of paragraph 28 of this Order.

- 30. Respondent shall train and educate any new employee(s), consistent with the requirements of this Order, within thirty (30) days of employment.
- 31. Respondent shall conduct annual training for all employees, management personnel current and new, consistent with the requirements of this Order.
- 32. Respondent shall document and maintain training and education materials, training records, test results, and other materials for all training required by paragraphs 28 through 31 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

Third Party Audit Provisions

- 33. Respondent shall, upon resumption of federal inspection services, cause to be made, by a qualified, independent third party, written audits of:
- (a) Respondent's implementation, monitoring, and maintenance of its sanitation, SSOP, HACCP and other process control, *Lm* sampling and testing, and other programs;
- (b) the effectiveness of Respondent sanitation, SSOP, HACCP, and other process controls, *Lm* sampling and testing, and other programs to ensure food safety;
 - (c) Respondent's compliance with FSIS statutory and regulatory requirements,
 - (d) Respondent's compliance with the terms of this Order; and
- (e) Each third-party audit shall include written findings and recommendations of the independent third party.
 - 34. 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;
- (b) subsequent audits shall be conducted every one hundred and eighty (180) calendar days thereafter for the duration of the Order.
- 35. Respondent shall prepare, for each audit conducted, a written response to the audit findings and recommendations. The Respondent's written response shall identify:
 - (a) any modifications to its SSOP, HACCP, Lm, or other programs or plans;
 - (b) any corrective actions implemented;
 - (c) any other actions implemented or planned in response; and
- (d) supportable information for any decision by Respondent to not implement any audit report recommendations.
- 36. Respondent shall submit a copy of each third-party audit, a copy of the Respondent's written response, or other documents relative to the audit to the Director, ELD for review and concurrence within thirty (30) days after each audit is completed.

Recordkeeping Provisions

- 37. Respondent shall maintain full, complete, and accurate written records of: (a) all records required to be maintained by the FMIA, PPIA, and the regulations; (b) all records required to be maintained under applicable Federal, State and local statutes; and (c) all SPS, SSOP, HACCP, *Lm* sampling and testing and other system(s), plans and records required by the FMIA, PPIA, the regulations, and this Order.
- 38. Respondent shall notify FSIS of any changes or modifications to its SSOP, HACCP, *Lm* sampling and testing program, or other systems, programs or plans, and all associated recordkeeping forms as required by the regulations or this Order.

General Compliance Provisions

- 39. Respondent or any of its owners, officers, directors, partners, employees, agents, successors, affiliates, or assigns shall not:
- (a) violate any section of the FMIA, the PPIA, or State or local statutes involving the preparation, sale, transportation or attempted distribution of any adulterated or misbranded meat or poultry products; or
 - (b) be convicted of any felony or fraudulent act;
- (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 duties;
- (d) conduct any operations requiring federal inspection outside the official hours of operation without obtaining prior written approval from FSIS.
- 40. Respondent shall fully and completely cooperate with any FSIS investigation inquiry, review, or examination of Respondent' compliance with the FMIA, PPIA or this Order.

Enforcement Provisions

41. The Administrator, FSIS, may summarily withdraw the grant of federal inspection from Respondent upon a determination by the Director of ELD that Respondent has committed an act in violation of, or failed to comply with one or more conditions set forth in paragraphs 1 through 40 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.

- 42. 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.
- 43. If any provision of this Order is declared invalid, such declaration shall not affect the validity of any other provision herein.
- 44. The provisions of this Order shall be applicable for a period of three (3) years from the effective date of this Order and shall become effective upon issuance by the Administrative







