

UNITED STATES DEPARTMENT OF AGRICULTURE  
BEFORE THE SECRETARY OF AGRICULTURE

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C-10-010HC  
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In re: }  
          } FMIA Docket No. 08-0002  
Scala Packing Company, Inc. }  
          } Respondent } Consent Decision  
          } }  
          } }

This is a proceeding 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 Scala Packing Company, Inc., hereinafter referred to as Respondent. This proceeding was commenced by a complaint filed on October 2, 2007 by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA).

The Respondent admits the findings of fact, as set forth herein, and specifically admits that the Secretary has jurisdiction in this matter. The Respondent neither admits nor denies the remaining allegations and waives oral hearing and further procedure. Respondent and its owners, officers, directors, partners, successors, assigns, and affiliates of Respondent, Scala Packing Company, Inc., waive any claim against complainant under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) and waive other action against USDA or its employees in connection with this proceeding and the facts and events that gave rise to this proceeding. Respondent consents and agrees, for the purpose of settling this proceeding and for such purpose only, to the entry of this decision.

## Findings of Fact

1. Respondent is now and at all times material herein, a business organized and existing under the laws of the State of Illinois, operating as a meat processing facility at 351 West Huron Street, Chicago, Illinois, 60610-3691.

2. Respondent is now, and was at all times material herein, a meat processing plant under a grant of inspection pursuant to the Federal Meat Inspection Act (21 U.S.C. §§ 601 et seq.) (FMIA) designated as Official Establishment Number 01731M.

3. Pascal Scala, who resides at 600 River Road, Mt. Prospect, Illinois 60056 is, and at all times herein was, the president of Scala Packing Company, Inc.

4. (a) On November 11, 2006, the Food Safety and Inspection Service (FSIS) collected from Respondent's federal establishment, a sample of fully-cooked, sliced roast beef, a fully-cooked not shelf stable (i.e. "ready-to-eat") product produced by Respondent. This sample confirmed positive test results for *Listeria monocytogenes* (*Lm*), a dangerous microbial contaminant and adulterant in ready-to-eat meat food products.

(b) On or about January 11 and 12, 2007, Respondent conducted a *Lm* sampling, collecting samples from 29 environmental areas resulting in five (5) "presumptive" *Lm* findings.

(c) On or about February 15, 2007 to March 15, 2007, FSIS conducted a comprehensive Food Safety System Assessment (FSSA) at Respondent's facility to determine the cause of the presumptive *Lm* samples, and to analyze the design and execution of its HACCP plan, SSOP and its overall food safety system. On March 15, 2007, FSIS conducted a *Lm* sampling, collecting samples from 10 product contact surfaces, 10 non-contact environmental surfaces and three product samples, resulting in two laboratory positive *Lm* findings on a product contact surface and a non-contact environmental surface.

(d) On or about March 23, 2007, FSIS issued a Notice of Intended Enforcement Action (NOIE), officially notifying the Respondent of FSIS' intent to withhold the marks of inspection and suspend the assignment of inspectors at the establishment, in accordance with Section 500.4 of Title 9 of the Code of Federal Regulations (9 CFR § 500.4), based on the Respondent's failure to, *inter alia*, implement and maintain Sanitation Standard Operating Procedures (SSOP) and Hazard Analysis and Critical Control Point (HACCP) systems, and failure to control microbial contamination in ready-to-eat meat product production, as required by Section 8 of the FMIA (21 U.S.C. § 608) and Parts 416, 417 and 430 of Title 9 of the Code of Federal Regulations (9 C.F.R. § Parts 416, 417 and 430), resulting in conditions conducive to the growth and spread of pathogens that may cause product to become adulterated. The NOIE provided written notice to Respondent of the proposed enforcement action and the opportunity to demonstrate or achieve compliance.

(e) On or about March 27, April 3, and April 5, 2007, the Respondent provided written responses to the NOIE, including its plans for corrective and preventive actions to reassess and reevaluate its HACCP and SSOP plans, and to change procedures for operational sanitation procedures, and pre-operational sanitation protocol.

(f) On or about April 5, 2007, FSIS issued a Notice of Deferral, holding the proposed enforcement action in abeyance, pending assessment and verification by FSIS personnel that the Respondent effectively implemented and executed its proposed corrective and preventive actions. The written notice advised the Respondent that failure to maintain regulatory compliance could result in the suspension of inspected operations.

(g) On or about July 8, 2007, an FSIS sample obtained from Respondent's facility of a meat food product, Natural Italian Style Roast Beef, collected on June 29, 2007, tested positive for the presence of the pathogen *Lm*.

(h) On or about July 9, 2007, FSIS verbally notified and issued a written Notice of Suspension (NOS) to Respondent, in accordance with Section 500.4 of Title 9 of the Code of Federal Regulations (9 CFR § 500.4), suspending Respondent's RTE inspection operations at the establishment, based on, *inter alia*, the FSIS positive *Lm* result, repetitive *Lm* findings in ready-to-eat products and contact surfaces at Respondent's facility, and the Respondent's failure to effectively implement corrective actions, and failure to maintain effective SSOP and HACCP systems.

(i) On or about July 19, 23, and August 3, 2007, the Respondent provided written responses to the NOS, including its plans for corrective and preventive actions to reassess and reevaluate its HACCP and SSOP plans, and to change procedures for operational sanitation procedures, and pre-operational sanitation protocol.

(j) On or about August 3, 2007, based upon Respondent's written assurances, FSIS placed the suspension action in abeyance, in accordance with Section 500.5(e) of the Code of Federal Regulations (9 C.F.R. § 500.5(e)), enabling the plant to resume operations based on its stated dedication to perform corrective actions. The written notice advised the Respondent that failure to effectively implement and execute its proposed actions and maintain regulatory compliance could result in the suspension of inspected operations.

(k) On or about September 4, 2007, FSIS issued to Respondent written Notice of Reinstatement of Suspension, in accordance with Section 500.4 of Title 9 of the Code of Federal Regulations (9 CFR § 500.4), suspending Respondent's RTE inspection operations at the

establishment. The reinstatement of suspension was based upon an analysis of samples collected on August 27, 2007 confirming *Lm* positive findings on two product contact surfaces, and based upon a review of the Respondent's operations since November, 2006 that, *inter alia*, the Respondent failed to effectively implement corrective actions and failed to maintain effective SSOP and HACCP systems for *Lm* as required by Section 430.4 of Title 9 of the Code of Federal Regulations (9 C.F.R. § 430.4), and failed to prevent insanitary conditions or contamination of product or product contact surfaces.

(l) On or about September 12, 2007, Respondent provided written responses to the reinstatement of a NOS, including its plans for corrective and preventive actions to reassess and reevaluate its HACCP and SSOP plans, and to change procedures for operational sanitation procedures, and pre-operational sanitation protocol. On September 19, 2007, FSIS issued a letter to Respondent, stating that Respondent's written response failed to effectively address food safety concerns, including the failure to fully reassess its SSOP and HACCP plans, and failure to reassess the implementation and verification of programs controlling *Lm* and other pathogens of concern.

### **Conclusion**

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

### **Order**

1. Federal meat inspection services under the Title I of the FMIA are withdrawn from Respondent Scala Company, Inc., its owners, officers, directors, partners, successors, affiliates, or assigns, directly or through any corporate device, for a period of two (2) years beginning on the effective date of this Order; Provided, however, the withdrawal of inspection services shall be held in abeyance, and inspection services shall be provided to Respondent for so long as the

conditions set forth below, in addition to all other requirements for applicable inspection services, are met:

2. 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) Plan, *Listeria monocytogenes* (*Lm*) sampling and testing program, and other written sanitation, process controls, and sampling or testing programs; and (b) the physical and sanitary conditions of Respondent's establishment.

3. FSIS will conduct examination 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**

4. Respondent shall: (a) develop written procedures, including monitoring, corrective action, and recordkeeping procedures that the establishment will implement to operate and maintain respondent Scala's 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. § Parts 416.1 to 416.6), and ensure that meat and meat products prepared, stored and packed are not adulterated; and (b) routinely assess its written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrective actions, or repairs to the program or to the establishment premises, facility or equipment needed to ensure and maintain sanitary conditions.

### **Sanitation Standard Operating Procedures**

5. Respondent shall: (a) develop revised written sanitation standard operating procedures (SSOP) to describe the monitoring activities, recordkeeping, and other procedures that Respondent will conduct, implement and maintain, on a daily and ongoing basis, before, during, and after operations, in accordance with 9 C.F.R. § 416.11 to 416.16, to ensure sanitary conditions and prevent product adulteration; (b) implement and maintain, on a daily and ongoing basis, its SSOP system as provided in this Order and the regulatory requirements of 9 C.F.R. § 416 to ensure the prevention of unsanitary conditions and prevent product adulteration; (c) implement all corrective and preventive actions required by 9 C.F.R. § 416.15, routinely evaluate the effectiveness of its SSOP, and implement all modifications required by 9 C.F.R. § 416.14, as necessary, to ensure that regulatory requirements for the maintenance of sanitary conditions and the production and distribution of safe, wholesome, unadulterated, and properly labeled products in commerce are met.

### **Hazard Analysis and Critical Control Point (HACCP) Plan**

6. Respondent shall: (a) develop HACCP Plans to describe each system of process controls and procedures that Respondent will implement and utilize on a daily and on-going basis to control and prevent the introduction of food safety hazards into meat and meat food products. These plans shall address specific process controls and procedures within Respondent's HACCP system(s) (i.e. *Listeria monocytogenes* in post lethality process steps), 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 critical control point in the Fully Cooked, Not Shelf Stable process, and to ensure the prevention or elimination of such hazards or their reduction to undetectable levels; and (ii) measures to eliminate or reduce and control the

level of *L. monocytogenes* to prevent contamination of Respondent's finished RTE product, 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).

7. Respondent shall: (a) implement, validate and maintain on a daily and ongoing basis the HACCP system(s) and plan(s), as provided in this Order, in accordance with the requirements of 9 C.F.R. § Part 417; and (b) implement timely and appropriate corrective and preventive actions and reassess and modify its HACCP systems and plans as necessary to ensure that the regulatory requirements for the control and prevention of pathogens and the production and distribution of wholesome, unadulterated and properly labeled products in commerce are met, as required by and consistent with 9 C.F.R. § Part 417; and (c) conduct ongoing assessment, validation and testing of the adequacy of the critical control points, critical limits, monitoring and record-keeping procedures, and corrective actions set forth in the HACCP system(s) and plan(s), to ensure that the establishment's food safety systems remain validated over time, as required by 9 C.F.R. § Part 417.

**Listeria monocytogenes Sampling and Testing Program**

8. Respondent shall produce all ready-to-eat (RTE) products in conformity with an intensified sampling program for 28 days. Results will be evaluated by Respondent and the program will be subsequently adjusted as necessary.

9. Respondent shall develop and implement a written *L. monocytogenes* sampling and testing program for its RTE products, in accordance with 9 C.F.R. § 430. Respondent's *L. monocytogenes* program shall, at the minimum:

(a) include one of the three alternatives for the production of post-lethality exposed RTE product based on its control program for *L. monocytogenes*;

(b) include a testing program for food contact surfaces, finished RTE product, and non-contact environmental surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

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

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

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

(f) include random sampling for all facility sites and production days that will give an equal opportunity of selection for all sites and times; and

(g) describe the conditions under which the establishment will implement hold and test procedures following a positive test of a food contact surface, finished RTE product, or a non-contact environmental surface for *L. monocytogenes* or an indicator organism.

10. In the event of any positive *L. monocytogenes* test result for food contact surfaces, non-contact environmental surfaces, or RTE products, Respondent shall immediately suspend RTE operations, and:

(a) prior to the resumption of RTE operations, shall:

i) take all necessary corrective and preventative measures to address the *L. monocytogenes* positive finding;

ii) reassess their *L. monocytogenes*, SSOP, and HACCP programs to determine if modifications need to be made to address preventative and corrective measures;

iii) document appropriate corrective and preventive actions;

iv) retrain employees in the *L. monocytogenes* program if in Respondent's reassessment it is determined that the contamination was due to employee practice or actions;

v) document any employee training; and

vi) if due to positive *L. monocytogenes* findings on food contact surfaces or RTE products, submit its proposed corrective actions, preventative measures and any changes to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans to FSIS for review and verification.

(b) In the event of any positive *L. monocytogenes* test results for non-contact environmental surfaces, after resumption of operations, submit its proposed corrective actions, preventative measures and any changes to its SSOP, HACCP, *Lm* sampling and testing program or other systems, programs or plans to FSIS for review and verification.

(c) upon resumption of operations, verify the adequacy of all corrective actions and preventative measures and the implementation of all procedures as documented under subparagraphs (a)(iii) and (a)(v).

(d) if the positive *L. monocytogenes* is found on a RTE products, modify its *L. monocytogenes* program to incorporate a post lethality treatment – or an antimicrobial agent or process that suppresses or limits the growth of *Lm*, in accordance with 9 CFR § 430.

(e) notify the FSIS District Manager and/or designee 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.

11. Respondent shall designate in writing, subject to the concurrence of the FSIS District Manager, one full time person and one alternate who shall be responsible for conducting sampling or other activities under its *L. monocytogenes* program and 9 C.F.R. § 430.

12. Respondent shall document and maintain sample laboratory results and records regarding the implementation and monitoring of its *L. monocytogenes* program, including corrective actions, regulatory records, and preventive measures, in accordance with 9 C.F.R. § 417.5, and make these plant records available to FSIS personnel for review and/or copying immediately upon request.

**Personnel**

13. Within thirty (30) days of the effective date of this Order and subject to the verification of the FSIS District Manager, Respondent shall designate in writing, one full-time person and one alternate person who shall be responsible for overall implementation, coordination, monitoring, verification, validation, reassessment, recordkeeping, review, and maintenance of the establishment's food safety and sanitation programs and the requirements of this Order.

**Establishment Training**

14. Within thirty (30) days of the effective date of this Order and subject to the verification of FSIS District Manager the Respondent shall: (a) develop a training program for all current employees and management personnel 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 procedures relevant to each employee's position; and

(b) train all current employees and management personnel in all aspects of food safety measures and regulatory requirements of SPS, SSOP, HACCP, *Lm* sampling and testing, recordkeeping procedures and the terms and conditions of this Order.

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

16. Respondent shall conduct annual training for all employees, management personnel current and new, consistent with the requirements of this Order.

**Recordkeeping.**

17. Respondent shall maintain full, complete and accurate written records of (a) all records required to be maintained by the FMIA 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 or testing of products and other systems, plans and records required by the FMIA, the regulations, and this Order.

18. Respondent shall notify the FSIS District Manager and/or designee 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 Provisions.**

19. 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 PPLA, State or local statutes involving the preparation, sale, transportation or attempted distribution of any adulterated or misbranded meat or poultry products;

(b) willfully make, or cause to be made, any false entry in any account, record, or memorandum kept by Respondent in compliance with applicable Federal or State statutes or regulations; or willfully neglect or fail to make full, true and correct entries in such accounts,

records or memoranda; or fail to keep such accounts, records or memoranda that fully and correctly disclose all transactions in Respondent's business;

(c) commit any felony or fraudulent criminal act that results in a conviction; or assault, intimidate, or interfere with; or threaten to assault, intimidate, or interfere with any program employee in the performance of his or her official duties under the FMIA and PPIA; or

(d) knowingly hire or add any new individual who has been convicted, in any Federal or State court, of any felony, or more than one misdemeanor based upon the acquiring, handling, or distributing of unwholesome, mislabeled or deceptively packaged food, or fraud in connection with transaction in food; and shall immediately terminate its connection with any such individual when that individual's conviction becomes known to Respondent.

**Enforcement Provisions.**

20. The Administrator, FSIS, shall have the right to withdraw inspection services, after a hearing pursuant to the USDA Rules of Practice in 7 C.F.R. § 1.141, upon a determination by the Director, EED, or his or her designee, that Respondent has violated any conditions set forth in this Order.

21. Notwithstanding paragraph 20, the Administrator, FSIS, shall have the right to summarily withdraw inspection services from Respondent's Ready to Eat Process upon a determination by the Director, EED, or his or her designee, that Respondent has violated any of the conditions within paragraphs 8 through 11 of this Order or that Respondent's food safety programs and systems have not been effective to eliminate or prevent *Lm* in finished RTE product, food contact surfaces or non-contact environmental surfaces at the establishment. Respondent retains the right to request an expedited hearing pursuant to the USDA, Rules of

Practice in 7 C.F.R § 1.141, concerning any violation alleged as the basis for the withdrawal of inspection services.

22. The Administrator, FSIS, shall have the right to summarily withdraw inspection services from Respondent upon a determination by the Director, EED, or his or her designee, that Respondent has shipped adulterated meat or poultry products in commerce. Respondent retains the right to request an expedited hearing pursuant to the USDA, Rules of Practice in 7 C.F.R. § 1.141 concerning any violation alleged as the basis for a summary withdrawal of inspection services.

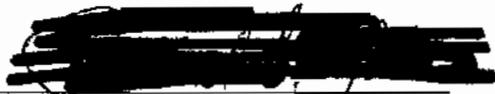
23. Nothing contained in these provisions precludes the right of FSIS to suspend operations at Respondent pursuant to 9 C.F.R. § 500. Nothing contained in these provisions prevents the right of Respondent to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. § 306.5 and 381.35.

Nothing in this Consent Decision shall preclude: (a) any pending or future criminal, civil, regulatory or administrative action authorized by law, regulation or otherwise; or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

24. If any provision of this Consent Decision is declared invalid, such declaration shall not affect the validity of any other provision herein.

25. This Consent Decision shall become effective upon issuance by the Administrative Law Judge.

26. This Consent Decision shall be effective for a period of two (2) years upon issuance by the Administrative Law Judge.

  
Pascal Scala, Owner

  
Scott C. Safian, Director

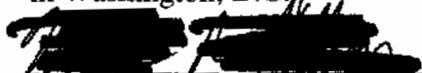
Scala Packing Company, Inc.

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Issued this 12<sup>th</sup> day of March 2008  
in Washington, D.C.

  
ADMINISTRATIVE LAW JUDGE