

UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE

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In re:

Sardinha Sausage

Respondent

}
} FMIA Docket No. 04-0006
} PPIA Docket No. 04-0007
}
}
}
} *Consent Decision*

This is a proceeding under the Federal Meat Inspection Act, as amended (21 U.S.C. § 601 et seq.) ("FMIA") and the Poultry Products Inspection Act, as amended (21 U.S.C. § 451 et seq.) ("PPIA") 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 Sardinha Sausage, hereinafter referred to as Respondent. This proceeding was commenced by a complaint filed on May 28, 2004 by the Administrator of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture (USDA), which is responsible for the administration of Federal inspection services for both meat and poultry. The parties have agreed that this proceeding should be terminated by entry of the Consent Decision set forth below and have agreed to the following stipulations:

1. For the purpose of this stipulation and the provisions of this Consent Decision only, Respondent admits all jurisdictional allegations of the complaint and waives:
 - (a) Any further procedural steps except as specified herein;
 - (b) Any requirement that the final decision in this proceeding contain any findings and conclusions with respect to all material issues of fact, law, or discretion, as well as the reasons or bases thereof; and
 - (c) Except as set forth herein, rights to seek judicial review or to otherwise challenge or contest the validity of this decision.

2. This Stipulation and Consent Decision is for settlement purposes only and does not otherwise constitute an admission or denial by Respondent that Respondent violated the regulations or statutes involved.

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

4. Respondent, its owners, officers, directors, partners, successors, assigns, and affiliates waive, in addition to the action waived in paragraph three above, any other action against USDA or its employees in connection with these proceedings.

Findings of Fact

1. Sardinha Sausage is an unincorporated business located at 206 Brownell Street, Fall River, Massachusetts, 02720.

2. Respondent has at all times material herein been granted Federal inspection services under the FMIA and PPIA under Establishment number 17995/ P-17995.

3. Edward Sardinha, at all times material herein, is the President and Owner of Sardinha Sausage.

4. On April 15, 2004, FSIS reinstated the suspension of federal inspection services issued to Respondent on December 18, 2003, based on Respondent's repetitive failures to meet Sanitation Standard Operating Procedures (SSOP), Sanitation Performance Standards (SPS) and Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) and *Listeria monocytogenes (Lm)* regulatory requirements of 9 C.F.R. Parts 416, 417 and 430.

Conclusion

Because the parties have agreed to the provisions set forth in the following Stipulation and Consent Decision in disposition of this proceeding, the following Order will be issued.

ORDER

Inspection services under the FMIA and PPIA are withdrawn from Respondent, **Sardinha Sausage**, its owners, officers, directors, partners, successors, affiliates, or assigns, directly or through any corporate device, for a period of three (3) years beginning on the effective date of this Order. Said withdrawal of inspection services shall be held in abeyance and inspection services shall be reinstated and provided to Respondent, pursuant to a conditional grant of inspection, for so long as, in addition to all other requirements of inspection services, the additional conditions set forth herein and below are met.

1. Respondent shall demonstrate, prior to the resumption of inspection services and to the satisfaction of FSIS, compliance with FSIS statutory and regulatory requirements, including, but not limited to, 9 CFR Parts 416, 417 and 430, upon a review and examination of Respondent's written Sanitation Standard Operating Procedures (SSOP), Hazard Analysis and Critical Control Point (HACCP), Sanitation Performance Standards (SPS), *Listeria monocytogenes (Lm)* and other sanitation or process control plans and programs and upon a review of the physical and sanitary conditions of the establishment.

I.

Sanitation Performance Standards

2. Respondent shall 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 SPS regulations (9 CFR 416.1 to

416.6), and ensure that meat and poultry products prepared, stored and packed are not contaminated or adulterated.

3. Respondent shall, prior to resumption of inspection services, make such facility repairs and improvements as necessary to ensure sanitary conditions and compliance with SPS, including, but not limited to:

- (a) replacing the coil drain pan of the refrigeration unit;
- (b) repairing the wall in the packaging cooler; and
- (c) repairing the screen doors in the shipping and receiving area.

4. Respondent shall demonstrate, prior to the resumption of inspection services and pursuant to paragraph 1 of the Order, that its premises, facilities and equipment meet the regulatory requirements of 9 CFR Part 416.1 to 416.6. Respondent shall address and repair, prior to resumption of inspection operations, any premises, facility and/or equipment issues, identified by FSIS at the time of the physical plant review conducted pursuant to paragraph 1, that do not comply with FSIS regulatory requirements.

5. Respondent shall implement and maintain “plant improvement procedures (PIP) to ensure maintenance of its premises, facilities, and equipment to ensure sanitary conditions and compliance with 9 CFR 416.1 to 416.6. Respondent shall monitor these procedures, and implement necessary, timely, and appropriate repairs and improvements as needed to ensure and maintain ongoing compliance with 416.1 to 416.6. Respondent shall record and maintain records of the implementation and monitoring of its PIP program and any repairs and/or improvements made, and shall make these records available to FSIS personnel for review and/or copying immediately upon request.

II.

Sanitation Standard Operating Procedures

6. Respondent shall, prior to resumption of inspection services, reassess and revise its SSOP, in accordance with 9 CFR Part 416, to describe the procedures conducted before, during and after operations to ensure sanitary conditions and prevent product contamination and/or adulteration. Respondent's revised SSOP shall address specific procedures, including, but not limited to:

- (a) accumulation of condensation and excessive build-up water from cleaning procedures on ceilings, and the prevention of contamination of exposed products and exposed contact surfaces during cleaning procedures; and
- (b) identify daily SSOP records sufficient to document the implementation and monitoring of the SSOP.

7. Respondent shall, prior to the resumption of inspection services and pursuant to paragraph 1 of the Order, submit such documents and procedures identified in paragraph 6 to demonstrate that its SSOP meets regulatory requirements of 9 CFR Part 416.

8. Respondent shall, upon resumption of inspection services, implement and maintain its SSOP procedures, in accordance to 9 CFR Part 416, to ensure the prevention of insanitary conditions and operations which can lead to direct product contamination, insanitary conditions or adulteration. Respondent shall implement and monitor specific procedures, including, but not limited to:

- (a) direct product contamination and contamination of product contact surfaces of processing utensils and equipment;

- (b) cross contamination of raw and ready-to-eat products in the operating environment, specifically, tempering of products, processing of products, storage of products, and retail products vs. inspected products;
- (c) accumulation of condensation and excessive water or build-up of water on refrigeration units, stagnant water on floors, and excessive water from cleaning procedures, including on ceilings, exposed products and exposed contact surfaces;
- (d) proper handling, storage, denaturing, and disposal of inedible products, in accordance with 9 CFR 325.13 and 416.3 (c);
- (e) the sanitation and monitoring of the outside premises to prevent the creation of insanitary conditions,
- (f) employee training program which covers all aspects of the SSOP and relative information for proper and effective sanitation procedures.

9. Respondent shall, upon resumption of inspection services, implement corrective and preventive actions, as required by 9 CFR 416.15, and routinely evaluate the effectiveness of its SSOP and implement necessary modifications, as required by 9 CFR 416.14, as necessary to ensure that regulatory requirements for the maintenance of sanitary conditions and the production and distribution of safe, wholesome, not adulterated and properly labeled products in commerce are met.

10. Respondent shall, as part of daily operation of its SSOP, document and maintain records regarding the implementation and monitoring of the SSOP procedures, and corrective and preventive actions. Respondent shall make its SSOP and SSOP record(s) available to FSIS personnel for review and/or copying immediately upon request.

III.

Hazard Analysis and Critical Control Point

11. Respondent shall, prior to resumption of inspection services, reassess and revise its HACCP system and the prerequisite programs that support the HACCP system, in accordance with requirements of 9 CFR Part 417. Respondent shall, revise the Fully Cooked, Not Shelf Stable HACCP plan to include process controls and procedures including, but not limited to:

- (a) all meat and poultry products shall be included in the process description, i.e. Calzones;
- (b) a flow chart describing each process step and product flow in the Respondent's production process, i.e. "Slicing";
- (c) conduct a hazard analysis for each process step to identify biological, chemical, and physical hazards that may or may not likely occur during the production process which may require controls, i.e. "Slicing";
- (d) a flow chart and hazard analysis showing a correlation between process steps, i.e. "Refrigerated Storage Packed Product";
- (e) the hazard analysis process step, "Receiving Beef By-Products (beef blood)" shall include justification for the Respondent's decision of identified biological hazards that are not likely to occur during the production process;
- (f) the hazard analysis process step, "Receiving Packaging Materials" shall identify chemical hazards, and Respondent shall determine whether the hazards are likely or not likely to occur during the production process that may require controls;
- (g) the hazard analysis process step, "Rework" shall identify biological, chemical, and physical hazards, and Respondent shall determine whether the hazards are likely or not likely to occur during the production process that may require controls;

(h) the hazard analysis process steps, “Fabrication and “Formulation shall identify biological hazards that are not likely to occur during the production process, i.e.

Salmonella spp., E.coli;

(I) the hazard analysis process step, “Weigh Pack and Label (post lethality step) shall identify the biological hazard, *Listeria monocytogenes*, that are likely or not likely to occur during the production process that may require controls;

(j) the HACCP plan’s critical control point “Cook/Smoke Sausage Products shall identify critical limits for all products prepared;

(k) the HACCP plan shall identify Respondent’s recordkeeping system for corrective action;

(l) the HACCP plan’s critical control point records shall indicate all parameters of the critical limits to be monitored;

(m) the HACCP plan shall include technical, scientific, and/or in-plant study supporting documentation to validate the effectiveness of the critical limits in controlling identified hazards;

(n) the HACCP plan shall ensure proper labeling of finished products with identity and code dates that include an expiration date, sell-by date, use-by date, or production date, etc. using a dating system according to company procedures, to provide means for product trace back and recall; and

(o) the HACCP plan’s critical control point record shall indicate on-going verification activity for direct observations of corrective actions.

12. Respondent shall, prior to resumption of inspection services, revise the Raw Not Ground HACCP plan to include process controls and procedures including, but not limited to:

- (a) the product ingredient list shall identify all spices and flavoring used in the preparation of products, i.e. salt;
- (b) the flow chart and hazard analysis shall show a correlation between process steps, i.e. “Rework ;
- (c) the hazard analysis process steps which identify hazards not likely to occur during the production process shall include supporting documentation as justification for the decision, i.e. process step “Tumbling ;
- (d) the HACCP plan critical control point “Weigh-Pack Label shall include monitoring the process step duration time, and the critical limit of 45°F to ensure product safety;
- (e) the HACCP plan shall identify and increase the monitoring frequency of the critical limit to ensure that the procedure will indicate that the critical control point is under control; and
- (f) the HACCP plan’s critical control point record shall indicate on-going verification activity for direct observations of corrective actions.

13. Respondent shall, prior to the resumption of inspection services and pursuant to paragraph 1 of the Order, submit such documents and procedures as identified in paragraphs 11 and 12 to demonstrate that its HACCP systems meets regulatory requirements of 9 CFR Part 417 and to ensure that the HACCP plans are science-based process controls to prevent, reduce, or eliminate food safety hazards that can pose a public health risk.

14. Respondent shall, upon resumption of inspection services, implement and maintain on a daily and on-going basis its HACCP system in accordance with 9 CFR Part, 417, including, but not limited to the procedures identified in paragraphs 11 and 12 and procedures for:

- (a) monitoring of critical control points and critical limits;

- (b) following corrective actions and preventive measures in response to a deviation from a critical limit;
- (c) on going verification activities, to include, but not limited to: calibration process monitoring instruments, direct observation of monitoring procedures and corrective actions, and review of records;
- (d) pre-shipment review for all products produced; and
- (e) recordkeeping of HACCP supporting documents and records.

15. Respondent shall implement timely and appropriate corrective and preventive actions as required by 9 CFR 417.3 and reassess and modify its HACCP system as necessary to ensure that the regulatory requirements for the control and prevention of pathogens, and the production and distribution of wholesome, not adulterated and properly labeled products in commerce are met, in accordance with 9 CFR Part 417.

16. Respondent shall document and maintain records regarding the implementation and monitoring of its HACCP system(s), and corrective and preventive actions in accordance with 9 CFR Part 417. Respondent shall make all plant and regulatory record(s) relative to its HACCP system(s), including supporting information and data for its hazard analysis or other decision making documents, available to FSIS personnel for review and/or copying immediately upon request.

IV.

Listeria monocytogenes Sampling and Testing Program

17. Respondent shall, prior to resumption of inspection services, reevaluate and revise its *Lm* sampling and testing program for ready-to-eat (RTE) products, in accordance with 9 CFR Part 430. Respondent's revised *Lm* program shall, at the minimum, include:

- (a) a flow chart indicating RTE products that had been exposed to food contact surfaces which tested positive for *Lm*, shall be condemned; and
- (b) include all food contact surface sites and equipment in the post lethality ready-to-eat environment, i.e. “Slicer .

18. Respondent shall, prior to the resumption of inspection services and pursuant to paragraph 1 of the Order, submit such documents and procedures as identified in paragraph 17 to demonstrate that Respondent’s *Lm* program meets regulatory requirements of 9 CFR Part 430 to prevent RTE products from adulteration by the pathogenic environmental contaminate *Listeria monocytogenes*.

19. Respondent shall, upon resumption of inspection services, implement and maintain its science-based *Lm* program, including the procedures identified in paragraph 17, for testing of food contact surfaces, non-contact surfaces, and RTE products in accordance with 9 CFR Part 430. Said *Lm* program shall include random sampling for all facility sites and production days that will give an equal chance of selection for all sites and times.

20. Respondent shall, in the event of any positive *Lm* test result for food contact surfaces, non-contact surfaces or RTE products;

- (a) document and implement appropriate corrective and preventive actions;
 - (b) reassess its *Lm* program, SSOP and HACCP programs;
 - (c) take appropriate action to identify and eliminate the source of the *Lm* contamination;
- and
- (d) monitor and verify the effectiveness of the corrective actions and preventive measures identified and implemented.

21. Respondent shall document and maintain sample laboratory results and records regarding the implementation and monitoring of its *Lm* program, and corrective actions and preventive measures in accordance with 9 CFR 417.5. Respondent shall make its *Lm* program, plant record(s), and regulatory record(s), including laboratory test results, regarding its *Lm* program available to FSIS personnel for review and/or copying immediately upon request.

V.

Prerequisite Programs

22. Respondent shall, prior to resumption of inspection services, revise its prerequisite programs that support its HACCP systems and control potential food safety hazards that are not likely to occur during the production process. Respondent's revised prerequisite programs shall incorporate process controls and procedures that include, but are not limited to:

- (a) a designated person that will perform the procedures specified in the programs;
- (b) detailed procedures to be conducted, their frequency, and measurable limits in which controls ensure product safety;
- (c) actions that will be taken if the procedures are not performed according to the written programs;
- (d) detailed corrective actions;
- (e) document results of the procedures and maintain a recordkeeping system for verification of compliance, as related to each HACCP plan; and
- (f) supporting documentation to ensure the effectiveness and adequacy of the prerequisite programs.

23. Respondent shall, prior to the resumption of inspection services and pursuant to paragraph 1 of the Order, submit such documents and procedures as identified in paragraph 22 to

demonstrate that its prerequisite programs meet regulatory requirements of 9 CFR 417.5(a)(1) to support its HACCP plan hazard analysis, and process steps which indicate hazards that are not likely to occur during the production process.

24. Respondent shall, upon resumption of inspection services, implement and maintain its prerequisite programs identified in paragraph 22. Respondent shall make its prerequisite programs, and record(s) available to FSIS personnel for review and/or copying immediately upon request.

VI.

Retail Product Prerequisite Program

25. Respondent shall, prior to resumption of inspection services, revise its retail product prerequisite program to ensure that no retail products will be returned to the federally inspected area of the facility for packaging.

26. Respondent shall, prior to the resumption of inspection services and pursuant to paragraph 1 of the Order, submit such documents and procedures as identified in paragraph 25 to demonstrate that its retail prerequisite program will ensure adequate handling and storage of products returned from the retail area.

27. Respondent shall, upon resumption of inspection services, implement and maintain procedures that, including, but not limited to:

(a) ensure all products produced under federal inspection transported to the retail area (retail store) will be labeled and include the federal mark of inspection;

(b) ensure no retail products are returned to the federally inspected area of the facility for production purposes, including packaging;

- (c) ensure that products that require storage in the federal inspected cooler(s) will be segregated from federally inspected products and labeled “For Retail Use Only ; and,
- (d) prior to the retail store operations, ensure the retail area will be sanitary cleaned, and assessable for FSIS personnel review and comment.

28. Respondent shall monitor, document, and maintain records of the retail prerequisite program, and shall make all such records available to FSIS personnel for review and/or copying immediately upon request.

VII.

Establishment Management and Personnel

29. Respondent shall, prior to resumption of inspection services, designate in writing, subject to the concurrence of the FSIS District Manager, one full-time person and one alternate who shall be responsible for overall implementation, coordination, monitoring, verification, validation, reassessment, record keeping, review and maintenance of the establishment’s PIP, SPS, SSOP, and HACCP programs, and for conducting and maintaining its *Lm* testing program, as required by and consistent with 9 CFR Parts 416, 417 and 430 and the requirements of this Order.

30. Respondent shall, prior to resumption of inspection services, provide the FSIS District Manager with written documentation, for his or her concurrence, of the designation of the responsible official(s) identified in paragraph 29.

31. Said designee(s) shall have full and independent authority to directly manage the plant’s daily operations related to all matters regulated by the FMIA and PPIA, including, but not limited to, the authority and responsibility to (a) communicate directly with FSIS personnel at all

levels; (b) make oral and written responses to noncompliance records and appeal the findings of FSIS program personnel; (c) slow, hold up or stop production; (d) remove product from production; (e) take positive control of any manufactured or stored product which is believed to be adulterated, misbranded or otherwise unsafe; (f) make decisions concerning product disposition, including product destruction; (g) recall any potentially adulterated or misbranded product that has reached any distribution channel; (h) make decisions concerning product labeling; (I) conduct or supervise the preparation of records, monitoring, verification or other production and regulatory procedures; and (j) take immediate corrective action(s), in accordance with 9 CFR Parts 416, 417 and 430, for deviation(s) or noncompliance(s) related to the plant's sanitation and food safety programs.

32. Said designee(s) shall be available to FSIS program personnel whenever processing or other inspected operations are being conducted, and Respondent may not conduct any operations requiring inspection in the absence of said designee(s).

33. Said designee(s) shall have completed, prior to the resumption of inspection services, a course of instruction in HACCP, SSOP, and be trained in the *Lm* sampling and testing procedures that complies with the requirements of 9 CFR 417.7.

34. Respondent may name a new designated official(s) at any time upon written request to and subject to the written concurrence of the FSIS District Manager.

35. Respondent shall maintain documentation of compliance with paragraphs 29 through 34 for the duration of the Order and make such records available to FSIS personnel for review and/or copying immediately upon request.

VIII.

Training and Education

36. Respondent shall, within twenty (20) days of resumption of inspection services, train and educate current employees in all aspects of food safety measures and regulatory requirements, including the requirements of the PIP, SPS, SSOP, HACCP and the *Lm* programs relevant to that employee's position. Respondent shall make the training and education materials available to FSIS personnel for review and/or copying immediately upon request.

37. Respondent shall train and educate any new employee, consistent with the requirements of paragraph 36, within (10) days of their employment.

38. Respondent shall conduct ongoing training and education of its employees, consistent with the requirements of paragraph 36, at least annually.

39. Respondent shall, prior to resumption of inspection services, name in writing, with the concurrence of the FSIS District Manager, the individual(s) responsible for the training and education of current and new employees required by paragraphs 36 to 38. The designated individual(s) shall have completed a course of instruction in the application of HACCP principles that complies with 9 CFR 417.7. Respondent shall, prior to resumption of inspection services, provide documentation that said individual(s) has completed the required HACCP certification, and make such documents available to the FSIS upon request.

40. Respondent may change the identified individual(s) upon written concurrence of the FSIS District Manager.

41. Respondent shall document and maintain written records of the implementation and completion of the initial and annual training for current and new employees for the duration of this Order, and make these records available to FSIS personnel for review and/or copying immediately upon request.

IX.

Third Party Audits and/or Assessment

42. Respondent shall, upon resumption of inspection services, cause to be made, by a qualified, independent third party, written audits and/or assessments of Respondent's (a) implementation, monitoring and maintenance of its PIP, SPS, SSOP, HACCP and *Lm* programs; (b) the effectiveness of its PIP, SPS, SSOP, HACCP and *Lm* programs to ensure food safety; (c) compliance with FSIS statutory and regulatory requirements; and, (d) compliance with the terms of this Order. Respondent's independent third party auditor must have successfully completed a course of instruction in the application of the seven HACCP principles, in accordance with 9 CFR 417.7. The written audits and/or assessments shall include a report of findings and recommendations, if any, of the independent third party.

43. The first assessment shall be conducted within sixty (60) days from the effective date of this Order. Thereafter, additional assessments shall be conducted at each one-hundred and eighty (180) day interval.

44. Respondent shall prepare, for each assessment conducted, a written response to the third party's findings and recommendations. Respondent's written response shall identify: (a) any modifications to its PIP, SPS, SSOP, HACCP or *Lm* programs; (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 recommendation of the third party.

45. Respondent shall make a copy of each third party assessment and a copy of Respondent's written response available to the FSIS for review and/or copying within thirty (30) days after each third party assessment is completed.

46. Respondent shall name in writing, subject to the concurrence of the FSIS District Manager, the third party responsible for conducting the independent assessments under this section. Provided, that the independent third party may not be a former or current employee of Respondent or any affiliated business or entity. Respondent may name a new independent third party, at any time, with the written concurrence of the FSIS District Manager.

X.

Record keeping

47. Respondent shall record and maintain complete and accurate written records of (a) all business activities applicable to the FMIA and PPIA and the regulations promulgated thereunder; (b) all PIP, SPS, SSOP and HACCP system records required by the FMIA, PPIA, regulations or the Order; and (c) all records, whether required by regulation, this Order, or otherwise, regarding the sampling or testing of products for *Lm* or other pathogens and the results of such sampling, testing or laboratory analysis.

48. Respondent shall, prior to resumption of inspection services, provide the FSIS District Manager with a copy of all record keeping forms to be used by Respondent in the conduct of activities regulated by the FMIA and PPIA and identify the purpose and use of each form. Respondent shall notify the FSIS of any changes or modifications to its record keeping forms or

system upon implementing any changes and provide copies of any new or modified forms to FSIS personnel for review and/or copying immediately upon request.

49. Respondent shall comply with all applicable Federal, State and local record keeping requirements related to its retail exempt activities and/or other federally inspected or State-regulated business or business activities.

50. Respondent shall make all records required by (a) the FMIA, PPIA, or the regulations promulgated thereunder, (b) Federal, State or local statute, or (c) this Order available to FSIS personnel for review and/or copying immediately upon request.

XI.

General Provisions

51. Respondent shall, prior to resumption of inspection services, submit a revised application for Federal Inspection, and upon resumption of inspection services, maintain its grant as required by 9 CFR 304.1.

52. Respondent shall, upon resumption of inspection services, immediately notify the FSIS District Manager and FSIS program personnel of any changes or modifications to its PIP, SPS, SSOP, HACCP systems or its *Lm* sampling and testing program.

53. Respondent, its officers, partners, employees, agents or affiliates shall not:

- (a) commit any felony or fraudulent act;
- (b) violate any section of the FMIA or PPIA;

- (c) violate any Federal, State or local statute involving the preparation, sale, transportation, distribution or attempted distribution of any adulterated or misbranded meat, poultry or food product or article;
- (d) supply labeling materials bearing Respondent's official mark for unauthorized use; or
- (e) assault, intimidate, impede, or interfere with, or threaten to assault, intimidate, impede, interfere with any USDA or FSIS employee(s) in the performance of official duties under the FMIA or PPIA.

54.. Respondent shall not conduct any operations requiring federal inspection outside the official hours of operation without obtaining prior written approval from FSIS program personnel.

55. Respondent shall fully and completely cooperate with any USDA or FSIS investigation, inquiry, review or examination of (a) Respondent's establishment, product or business records or (b) Respondent's compliance with the FMIA, PPIA, and the regulations promulgated thereunder, or (c) Respondent's compliance with this Order.

XII.

Enforcement

56. The Administrator, FSIS, may summarily withdraw federal inspection from Respondent upon a determination by the Administrator, FSIS, or the Director, Evaluation and Enforcement Division, Office of Program Evaluation, Enforcement and Review, FSIS, that Respondent has committed an act in violation of or failed to comply with any requirement of this Order.

57. Respondent retains the right to request an expedited hearing, pursuant to the applicable rules of practice (7 CFR Part, subpart H and 9 CFR Part 500), concerning any suspension action or the withdrawal of inspection service.

XIII.


Miscellaneous Provisions

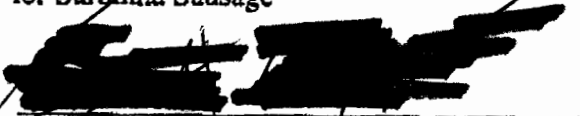
58. Nothing in this Order shall preclude (a) any future criminal, civil, regulatory or administrative action authorized by law, regulation or otherwise, including, but not limited to any action under the FSIS Rules of Practice (9 CFR Part 500) or (b) the referral of any matter to any agency for possible criminal, civil, or administrative proceedings.

59. If any provision of this Order is declared invalid, such declaration shall not affect the validity of any other provisions herein.

60. The provisions of this Order shall be applicable for period of three (3) years from the effective date of this Order.

This Consent Decision and Order shall become effective for a period of three (3) years upon issuance by the Administrative Law Judge.

 Pres. Owner.
Edward Sardinha, President and Owner
for Sardinha Sausage


Scott C. Safian, Director
Evaluation and Enforcement Division
Office of Program Evaluation,
Enforcement and Review
Food Safety and Inspection Service

[Redacted signature]

Margaret Burns, Esq
United States Department of Agriculture
Office of the General Counsel
Attorney for Complainant

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Krishna Ramaraju, Esq.
United States Department of Agriculture
Office of the General Counsel
Attorney for Complainant

Issued this 10 day of September 2004
at Washington, D.C.

[Redacted signature]

VICTOR W. PALMER
Administrative Law Judge