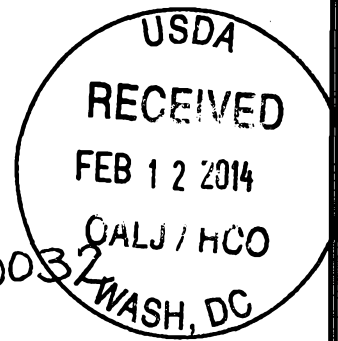


UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE SECRETARY OF AGRICULTURE



In re:

Mongiello Italian
Cheese Specialties, LLC, d/b/a/
Formaggio Italian Cheese Specialties,

Respondent

FMIA Docket No. 14-0032

Consent Decision

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 Respondent. This proceeding was commenced by a Complaint filed on November 14, 2013, 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. 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).

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. The Respondent and its owners, officers, directors, partners, successors, assigns, and affiliates waive any claim against Complainant under the Equal Access to Justice Act of 1980 (5 U.S.C. § 504 *et seq.*) and waive any other action against USDA or its employees in connection with this proceeding and the facts and events that gave rise to this proceeding. The Respondent consents and agrees, for the purpose of settling this proceeding and for such purpose only, to entry of this decision.

The Respondent agrees to the entry of this decision.

Findings of Fact

1. The Respondent is now, and was at all times material herein, a limited liability company organized and existing under the laws of the State of New York and operating as a meat processing facility at 250 Hilldale Road, Hurleyville, New York 12747.

2. On March 1, 2013, the Canadian Food Inspection Agency (CFIA) collected and tested 5 finished product samples of Respondent's Ready-to-Eat (RTE) meat food product known as "Artisan Wraps" from a shipment of Respondent's product. One of these samples tested positive for the adulterant *Listeria monocytogenes* (*Lm*), a microbial contaminant in the post-lethality RTE environment.

3. As a result of the positive *Lm* sample reported by the CFIA, on April 8, 2013, the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) assigned an Enforcement Investigation and Analysis Officer (EIAO) to conduct a Food Safety Assessment (FSA) at the Respondent's establishment.

4. On April 11, 2013, as part of the FSA, FSIS conducted routine risk-based *Lm* (*RLm*) testing within the Respondent's establishment. Sampling included 10 food contact surface swabs, 5 non-food contact surface swabs, and 5 finished product samples. The 5 non-food contact samples were tested as one environmental composite sample and the 5 product samples as one product composite sample. On April 17, 2013, the FSIS Eastern Laboratory returned confirmed positive *Lm* results for two direct product contact surfaces, and the composite environmental sample. On April 18, 2013, the same laboratory returned confirmed positive *Lm* results for the finished product composite sample.

5. On April 18, 2013, the Philadelphia District Office of FSIS issued a Notice of Suspension (NOS) to the Respondent in accordance with the Rules of Practice, 9 C.F.R. 500.3(a)(4). This NOS was based on the four (4) positive *Lm* results for the FSIS-collected *RLm* samples. The NOS was also based on: (1) the failure of the establishment to reassess its Hazard Analysis and Critical Control Points (HACCP) Program upon the creation of a second production line for "Artisan Wraps",

(2) failure of the establishment's HACCP flow chart to indicate use of rework product from the "Artisan Wrap" process within other production lines and products ("rolled meat and cheese logs"), (3) failure to implement adequate corrective actions in response to the CFIA product positive *Lm* test result, and (4) failure to maintain sanitary conditions on product contact surfaces eligible for *Lm* testing.

6. In response to the NOS, on April 19 – 22, 2013, the Respondent proffered corrective and preventive measures, including: (1) a revised HACCP Plan, (2) a revised Sanitation Standard Operating Procedure Program (SSOP) and (3) a revised *Lm* Control Program. Accordingly, on April 24, 2013, FSIS issued a Notice of Suspension held in abeyance pending verification of effective implementation and confirmation that the Respondent's revised HACCP, SSOP and *Lm* programs would be effective.

7. On May 29, 2013, FSIS issued a Notice of Intended Enforcement (NOIE) to the Respondent based on findings from the FSA conducted at the Respondent's establishment from April 8, 2013 through May 29, 2013. FSIS findings of non-compliance with HACCP requirements included: (1) undeclared allergen "isolated soy protein" in product "fresh mozzarella with chorizo and cilantro" which resulted in FSIS recall #30-2013, (2) failure to identify hazards, (3) failure to support critical limits, (4) failure to monitor critical limits, (5) failure to perform verification procedures, and (6) failure to monitor and support pre-requisite programs as effective. FSIS findings of non-compliance with SSOP requirements included: (1) failure to include all procedures necessary to prevent product adulteration, (2) failure to perform corrective actions, (3) failure to prevent the entrance of vermin, and maintain facilities in a sanitary condition, (4) failure to implement pre-operational inspection procedures, (5) failure to convey liquid waste from the facility, (6) failure to provide for adequate drainage of water from floors, (7) failure to disassemble equipment to the extent possible for cleaning and (8) failure to maintain outside grounds of Respondent's facility in a sanitary condition. Based on the Respondent's written responses during the period of May 29, 2013 through June 28, 2013, on July 3, 2013, FSIS deferred further enforcement action to allow the Respondent to

implement its proffered corrective and preventive measures.

8. On June 19, 2013, FSIS issued a Notice of Reinstatement of Suspension (NROS) to the Respondent in accordance with the Rules of Practice, 9 C.F.R. 500.3(a)(4). The NROS was issued due to the results of a June 12, 2013 FSIS risk-based RTE001 sampling of RTE product "Artisan Wraps," lot number 2515509, for project code 100500165, which tested positive for the adulterant *Lm*.

9. On June 25, 2013, FSIS held the NROS in abeyance after the Respondent implemented corrective and preventive measures. FSIS' decision to hold the NROS in abeyance afforded the Respondent a second opportunity to demonstrate compliance with the FMIA and the regulations promulgated thereunder.

10. On July 18, 2013, FSIS issued a Letter of Concern to the Respondent based on Pulsed-field Gel Electrophoresis (PFGE) pattern results of *Lm* samples referenced in paragraph (c) of section III, *supra*. These samples were returned with an identical PFGE pattern: GX6A16.1072/GX6A12.0209. The letter explained to the Respondent that the historical findings of *Lm* with an identical PFGE pattern provided evidence of likely and/or possible harborage of the adulterant *Lm* within the Respondent's establishment. The letter additionally noted that the potential for cross contamination from the harborage site to product contact surfaces was very strong. Finally, the letter advised the Respondent to consider further evaluation of its food safety system, including its testing programs, sanitation programs, employee practices, and previous corrective actions.

11. On July 30, 2013, FSIS issued a second Notice of Reinstatement of Suspension in accordance with the Rules of Practice, 9 CFR 500.3(a)(4). This NROS resulted from a sample taken by FSIS on July 24, 2013 of RTE "Artisan Wraps" Lot number 625204, for project code RTE001, which was confirmed by the FSIS Mid-Western Laboratory as positive for the adulterant *Lm*. This second NROS was held in abeyance on August 8, 2013, after the Respondent implemented corrective and preventive measures. FSIS' decision to hold the NROS in abeyance afforded the Respondent a third opportunity to demonstrate compliance with the FMIA and

the regulations promulgated thereunder.

12. On August 14, 2013, FSIS issued a Notice to Show Cause to the Respondent. This Notice to Show Cause indicated that FSIS was considering an action to withdraw federal inspection services based on a repetitive history of violations of food safety protocols, sanitation programs, pathogen control measures, and other issues.

13. On August 26, 2013, the United States Food and Drug Administration (FDA) conveyed results of sampling conducted at the Respondent's establishment on July 22, 2013, which included 9 *Lm* positives results of the 100 samples taken. All FDA positive samples were returned with a PFGE pattern identical to all positive samples taken previously by FSIS: GX6A16.1072/GX6A12.0209.

14. On September 19, 2013, a second FSIS-issued Letter of Concern was hand delivered to the Respondent based on PFGE pattern results of all prior *Lm* samples obtained by FSIS and FDA and referenced in paragraphs (c), (g), (j) and (l) of section III, *supra*; each of the aforementioned samples returned with an identical PFGE pattern: GX6A16.1072/GX6A12.0209. The letter explained to the Respondent that the historical findings of *Lm* with an identical PFGE pattern provides evidence of likely and/or possible harborage of the adulterant *Lm* within the Respondent's establishment. The letter additionally noted that the potential for cross contamination from the harborage site to product contact surfaces was very strong. Finally, the letter advised the Respondent to consider further evaluation of its food safety system, including its testing programs, sanitation programs, employee practices, and previous corrective actions.

15. In a letter dated October 21, 2013, FSIS, Office of International Affairs was notified by CFIA that a shipment consisting of 607 cases of the Respondent's RTE "Artisan Wraps," Import Certificate Number USCA2013063788, originating from Est. 34483 M and imported to Canada on October 3, 2013, was intercepted upon arrival and subjected to "hold and test" procedures. CFIA test results indicated *Lm* was detected in product samples from the shipment of Respondent's RTE "Artisan Wraps" represented by Import Certificate Number

USCA2013063788.

16. On October 23, 2013, upon receipt of the CFIA letter referenced in Paragraph (n), FSIS immediately proceeded to issue a third Notice of Reinstatement of Suspension due to the Respondent's continuing production and shipment of adulterated RTE product, as well as the Respondent's ineffective corrective actions as evidenced by the positive test results reported by the CFIA.

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 inspection services under the FMIA are withdrawn from the Respondent and its owners, officers, directors, successors, and assigns for a period of three (3) years beginning on the effective date of this Order. Provided, however, the withdrawal of federal inspection services shall be held in abeyance, and federal inspection services shall be provided to the Respondent for so long as the conditions set forth below, in addition to all other applicable requirements for federal inspection services, are met:

1. Prior to the resumption of federal inspection services, and subject to verification by FSIS, the 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 the 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 Provisions

3. Prior to the resumption of federal inspection services, and subject to verification by FSIS, the Respondent shall develop written procedures, including monitoring, corrective action, and recordkeeping procedures that the 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 meat food products prepared, stored, and packed 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 meat food products are not adulterated; and

(b) assess its written SPS procedures to evaluate their effectiveness, and make necessary improvements, corrective actions, 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 Provisions

5. Prior to the resumption of federal inspection services, and subject to verification by FSIS, the 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, the 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 and 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 insanitary conditions and the production and distribution of safe, wholesome, not adulterated, and properly labeled products in commerce are met.

Hazard Analysis and Critical Control Points (HACCP) System Provisions

7. Prior to the resumption of federal inspection services, and subject to verification by FSIS, the Respondent shall:

(a) reassess its HACCP system to describe each system of process controls and procedures that the Respondent will implement and utilize on a daily and on-going basis to control and prevent the introduction of food safety hazards in their meat and meat food products. These plans shall address specific process controls and procedures within the 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 the Respondent's finished RTE meat 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, the 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 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

(d) conduct ongoing assessment, validation, and testing of 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 Respondent's food safety system remains validated over time, as required by 9 C.F.R. Part 417.

Listeria monocytogenes Sampling and Testing Program Provisions

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 results;
- (d) alternative 3 for the production of post-lethality exposed RTE product;
- (e) testing for product, food contact surfaces, indirect contact surfaces, and 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

10. Upon resumption of federal inspection services, and subject to verification by FSIS, the Respondent shall implement a five (5) consecutive production days initial start-up production period intensified sampling and testing production schedule, to include:

(a) full establishment operations including but not limited to production of RTE meat products;

(b) intensified testing for product, food contact surfaces, indirect contact surfaces, and non-food contact surfaces during the full five (5) 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 food products produced until all laboratory results are received for five (5) 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 "Tier I (Environmental/non-food contact surface/ indirect non-food contact surface samples in any zone where RTE product is processed, stored, or held, and sites of previous positives, including Zone 1, 2, 3, 4, 5, 7, and 11)" random sampling and testing for five (5) sites per zone including two (2) common lines per shift for a total of thirty five (35) sites per regular eight (8) hours production day; in addition random sampling and testing of 5 sites from the other zones included in the establishment's monitoring program; (ii) For "Tier II (food contact surfaces/ in any zone where RTE product is exposed to the environment, including Zone 2, 3, 4, 5, and 7)" random sampling and testing for ten (10) sites per zone including two (2)

common lines for a total of fifty (50) sites per regular eight (8) hours production day; (iii) For "Tier III (Product Samples Zone 2 and 3)" twenty (20) samples from each two (2) common lines for a total of (40) random samples of final packaged product per regular eight (8) hours production day; and

(e) holding procedures for all products produced during the full five (5) consecutive production days initial start-up production period until all laboratory results are received for all five (5) consecutive production days, and information regarding all testing has been provided to FSIS for review, verification, and concurrence.

11. The Respondent may in the event of the successful completion of the initial start-up period for all five (5) consecutive days of production: (i) ship all RTE products produced during those five (5) 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 *L. monocytogenes* test result for product or food contact surfaces at any time during the five (5) consecutive production day initial start-up period Respondent shall immediately:

(a) suspend operations;

(b) destroy all products produced and held during the full five (5) production day 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 indirect contact surfaces or 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; and

(b) continue to hold all product 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 paragraphs 12 of this Order re-start its five (5) 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 five (5) consecutive production days.

Routine Production Sampling

15. The Respondent's routine production sampling and testing shall, at a minimum, include:

(a) testing and sampling frequency as follows: (i) For "Tier I (Environmental/non food contact surface/ indirect non-food contact surface samples in any zone where RTE product is processed, stored, or held, and sites of previous positives, including Zone 1, 2, 3, 4, 5, 7, and 11)" random sampling and testing for five (5) sites for each zone including two (2) common line on a daily basis to be taken at least three (3) hours into production, in addition random sampling and testing of 5 sites from the other zones included in the establishment's monitoring program for a total of forty (40) samples; (ii) For "Tier II (food contact surfaces/ in any zone where RTE product is exposed to the environment, including Zone 2, 3,4, 5, and 7)" random sampling and testing for seven (7) sites per zone including two (2) common lines for a total of thirty-five (35) sites per regular eight (8) hours production day; and (iii) For "Tier III (Product Samples Zone 2 and 3) Ten (10)" samples from the two (2) common lines for a total of (20) random samples of final packaged product from each common line per regular eight (8) hours production day;

(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*, in Zones 2 and 3 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 "Tier I (Environmental/non-food contact surface/indirect non- food contact surface samples in any zone where RTE product is processed, stored, or held, and sites of previous positives, including Zone 1, 2, 3, 4, 5, 7, and 11", 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 and test these sites in conjunction with any testing of the positive site in (b) above; and

(d) If any indirect or non-food contact surface re-test in (b) 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 19 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 19 of this Order.

Intensified Production Sampling

19. The Respondent's intensified production sampling and testing shall include, at a minimum:

(a) intensified testing for product, food contact surfaces, and 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 "Tier I (Environmental/non-food contact surface/ indirect non- food contact surface samples in any zone where RTE product is processed, stored, or held, and sites of previous positives, including Zone 1, 2, 3, 4, 5, 7, and 11)" random sampling and testing for five (5) sites per zone including two (2) common lines for a total of thirty five (35) sites per common line per regular eight (8) hours production day; (ii) For "Tier II (food contact surfaces/ in any zone where RTE product is exposed to the environment, including Zone 2, 3,4, 5, and 7)" random sampling and testing for ten (10) sample sites per zone including two (2) common lines for a total of fifty (50) sites per regular eight (8) hours production day; and (iii) For "Tier III (Product samples Zone 2 and 3)" Ten (10) samples from each two (2) common lines for a total of twenty (20) random samples of final packaged product per regular eight (8) hours production day; 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 Zones 2 and 3 and for product samples.

20. 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 employee 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.

21. In the event of any positive *Lm* test results for indirect contact surfaces or 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.

22. The Respondent shall, in the event of any positive *Lm* test results as described in paragraphs 20 or 21 of this Order, re-start its intensified production sampling as provided in paragraph 19 of this Order until negative results are received for one work week of production days.

23. The Respondent may continue operations, testing, and sampling for *Lm* under its routine production sampling program as provided in paragraphs 15 to 18 of this Order, upon receiving all laboratory reports verifying negative test results for all product and Tier II (food contact surfaces) for one work week of production days.

Laboratory Methods

24. The Respondent shall have all samples tested at its contract laboratory until such time that they can demonstrate to FSIS through companion sampling verification data that the Respondent's in-house testing protocols are equivalent to, or as effective as, the contract laboratory in identifying *Lm*. The Respondent shall submit such information to FSIS in writing for review, verification and concurrence.

25. The 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 plant records available to FSIS personnel for review and/or copying immediately upon request.

Employee Training Provisions

26. Prior to the resumption and subject to the verification of FSIS, the 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 employee's position.

27. Within forty-five (45) calendar days of the effective date of this Order and subject to verification by FSIS, the Respondent shall train all current employees consistent with the requirements of paragraph 26 of this Order.

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

29. The Respondent shall document and maintain training and education materials, training records, test results, and other materials for all training required by paragraphs 26 through 28 of this Order and make these records available to FSIS personnel for review and/or copying immediately upon request.

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

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

32. The Respondent shall document and maintain training and education materials, training records, test results, and other materials for all training required by paragraphs 26 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. The Respondent shall, upon resumption of federal inspection services, cause to be made, by a qualified, independent third-party, written audits of:

(a) the 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 the Respondent's sanitation, SSOP, HACCP, and other process controls, *Lm* sampling and testing, and other programs to ensure food safety;

(c) compliance with FSIS statutory and regulatory requirements,

(d) compliance with the terms of this Order; and

(e) any 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 (180) calendar days thereafter for the duration of the Order.

35. The 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 the Respondent to not

implement any audit recommendation.

36. The Respondent shall submit a copy of each independent third-party audit, a copy of the Respondent's written response, or other documents relative to the audit to the Director of the Enforcement and Litigation Division (ELD) for review and concurrence within thirty (30) days after each audit is completed.

Recordkeeping Provisions

37. The 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 systems, plans and records required by the FMIA, the regulations, and this Order.

38. The 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) commit any felony or fraudulent criminal act that results in a conviction.

Enforcement Provisions

40. The Administrator of FSIS may summarily withdraw federal inspection

Services upon a determination by the Director of ELD, or his or her designee, that one or more conditions set forth in paragraphs 1 through 39 of this Order have been violated.

It is acknowledged that the Respondent retains the right to request an expedited hearing pursuant to the rules of practice concerning any violation alleged as the basis for a summary withdrawal of federal inspection services. Nothing contained in these provisions prevents the right of the Respondent to appeal the decision of an FSIS employee to his/her immediate supervisor pursuant to 9 C.F.R. § 306.5.

41. 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.


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

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 Law Judge.


By:


Anthony Mongiello

President
Mongiello Italian Cheese Specialties,
LLC, d/b/a Formaggio Italian Cheese
Specialties


Scott C. Safian

Director, Enforcement and Litigation Division
Food Safety and Inspection Service
United States Department of Agriculture


Brian P. Sylvester, Esq.
Attorney for Complainant
United States Department of Agriculture
Office of the General Counsel
Marketing, Regulatory & Food Safety Programs Div.

Issued this 12 day of FEB, 2014
at Washington, D.C.


Administrative Law Judge
