UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	Case No. 2:14-cv-13077
	)	
v.	)	
	)	
S. SERRA CHEESE COMPANY, a corporation,	)	CONSENT DECREE FOR PERMANENT INJUNCTION
	)	
and	)	
	)	
FINA SERRA and STEFANO SERRA, individuals,	)	
	)	
Defendants.	)	
	)	

Plaintiff, United States of America, by its undersigned attorneys, having filed a complaint for permanent injunction against S. Serra Cheese Company ("Serra Cheese"), a corporation, and Fina Serra and Stefano Serra, individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree for Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 et seq.

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for

introduction, into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by doing an act that causes the adulteration, within the meaning of 21 U.S.C. § 342(a)(4), of articles of food while such articles are held for sale after shipment of one or more components in interstate commerce.

5. Upon entry of this Decree, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, holding, and distributing articles of food, at or from their facility located at 19717 15 Mile Road, Clinton Township, Michigan, and any other locations at or from which Defendants now or in the future, receive, prepare, process, pack, hold, or distribute any articles of food ("facility(ies)"), unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to collect product and environmental samples from within the facility(ies) and analyze those samples for the presence of *Listeria*, including *Listeria monocytogenes* ("*L. mono*"), in a method that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain certain provisions, acceptable to FDA, for regular environmental and

finished product sample collection and analysis, including how and where to sample, the number and frequency of samples to be collected, and the methods of analysis, in accordance with the *Listeria* Monitoring Program discussed in paragraph 5(C) below;

B. Defendants retain, at their expense, an independent expert(s) (the "sanitation expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to inspect Defendants' facility(ies) and to determine whether the methods, facility(ies), and controls are operated and administered in conformity with the Act and 21 C.F.R. Part 110. Defendants shall notify FDA in writing of the name(s) and qualifications of the sanitation expert(s) as soon as they retain such expert(s);

C. Defendants' sanitation expert, in consultation with the laboratory, after reviewing all FDA and Michigan Department of Agriculture & Rural Development ("MDARD") observations from January 2013 to present, develops a written *Listeria* Monitoring Program, which shall include, at a minimum, the following:

(1) An effective written sanitation control program that establishes adequate methods, facility(ies), and controls for receiving, preparing, processing, packing, holding, and distributing articles of food to minimize the risk of introduction of pathogenic *Listeria*, any other poisonous or deleterious substances, or filth, and to ensure that Defendants' foods are not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facility(ies), and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering the facility(ies) and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food to prevent such articles from becoming adulterated, and instituting standard sanitation operating procedures

("SSOPs") to ensure that the facility(ies) and equipment therein are continuously maintained in a sanitary condition;

(2) A written employee training program that includes, at a minimum, instruction on sanitary food handling techniques and documentation that each employee has received such training. Defendants' expert shall ensure that each employee fully understands the substance of the employee training program;

(3) An effective program of environmental monitoring and testing of the facility(ies) to ensure that microorganisms such as *Listeria*, any poisonous or deleterious substances, and filth are not present within the facility(ies). Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the facility(ies) (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing collected samples, in a manner acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) business days of receipt by Defendants; and

(4) A written plan for remedial action should pathogenic *Listeria*, any other poisonous or deleterious substance, or filth be detected;

D. Defendants assign continuing responsibility for the operation of the *Listeria* Monitoring Program to a person or persons who, by reason of background, experience, or education, is competent to maintain the facility(ies) in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

E. FDA approves, in writing, the *Listeria* Monitoring Program discussed in paragraph 5(C) prior to implementation;

F. The sanitation expert conducts a comprehensive inspection of the facility(ies), the methods and controls used to receive, prepare, process, pack, hold, and distribute foods to determine whether Defendants have effectively implemented all necessary corrections and are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The expert shall submit all findings to Defendants and FDA concurrently, within ten (10) business days after completion of the inspection;

G. Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with the Act and all applicable regulations, including:

(1) Documentation that Defendants have cleaned and sanitized the facility(ies) and equipment therein and made improvements, thereby rendering the facility(ies) and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and documentation that Defendants have received laboratory confirmation from environmental swabbing that *Listeria* is no longer present in the facility(ies); and

(2) Specific measures that they have taken to address each of the violations documented by FDA and MDARD since January 2013;

H. Within twenty (20) business days after entry of this Decree, Defendants shall, pursuant to a written destruction plan approved in writing by FDA, destroy under FDA's supervision all raw ingredients and all in-process and finished articles of food currently in their custody, control, or possession;

I. Defendants recall, to the retail level, and destroy all cheese distributed since November 8, 2013.

J. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and all applicable regulations, conducts inspections of the facility(ies), including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

K. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 5(A) through (I) of this Decree, the Act, and 21 C.F.R. Part 110; and

L. Defendants have paid all costs of inspection, analysis, review, investigations, examination, and supervision for FDA's oversight with respect to paragraphs 5(A) through (K), at the rates set forth in paragraph 11 below.

6. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of this Decree pursuant to paragraph 20 below, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

A. violates the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. violates the Act, 21 U.S.C. § 331(k), by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more components in interstate commerce; or

C. results in the failure to implement and continuously maintain the requirements of this Decree.

7. Immediately upon resuming operations after completing the requirements of paragraph 5 and receiving notice from FDA pursuant to paragraph 5(K), Defendants shall, in consultation with the laboratory and the sanitation expert, continuously implement the following steps to prevent adulteration of food received, prepared, processed, packed, or held in, and/or distributed from, their facility(ies):

A. Effectively implement, on an ongoing basis, the *Listeria* Monitoring Program developed pursuant to paragraph 5(C);

B. Conduct environmental monitoring and testing as set forth in paragraph 5(C)(3) to ensure that the SSOPs continue to eliminate the *Listeria* hazard and that the SSOPs are consistently followed. Environmental testing shall be performed by the laboratory in accordance with timetables and methods that Defendants submit in writing to FDA for prior written approval by FDA. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants.

Defendants' environmental testing must include, at a minimum, all of the following:

(1) if a food- or non-food-contact surface tests positive for *Listeria* during routine testing, intensified sampling must be initiated immediately, in conjunction with intensified sanitation measures. Intensified sampling requires that three (3) samples per day must be collected and analyzed until a total of nine (9) consecutive samples (three (3) days of intensified sampling) have tested negative for *Listeria* from the site where the *Listeria* was identified. After nine (9) consecutive samples have tested negative for *Listeria*, that site may be subject to routine sampling; and

(2) all food in contact with a site that tests positive for *Listeria* must be quarantined and tested for pathogenic *Listeria*. Food that tests negative for *L. mono* may be released from quarantine; food testing positive for *L. mono*, as well as all food manufactured since the positive laboratory sample(s) were collected, must be destroyed pursuant to a written destruction plan approved in writing by FDA. Defendants shall bear the costs of such destruction and the costs of FDA's supervision of such destruction, at the rates specified in paragraph 11; and

C. Conduct finished product testing in the following manner:

(1) Defendants shall test all lots of cheese for *L. mono* and *Escherichia coli* ("*E. coli*") for at least five consecutive production days using a testing method approved in advance by FDA;

(2) After the completion of testing under paragraph 7(C)(1), Defendants shall test at least one lot of each cheese per day for the next twenty (20) production days;

(3) After the completion of testing under paragraph 7(C)(2), Defendants shall test at least one lot of each cheese every five (5) production days for the next three (3) months; and

(4) After the completion of testing under paragraph 7(C)(3), Defendants shall test at least one lot of each cheese monthly thereafter.

(5) If any cheese tested pursuant to paragraphs 7(C)(1)-(4) is positive for non-pathogenic *E. coli* at levels greater than 10 most probable number (MPN) per gram in two or more subsamples, or greater than 100 MPN per gram in one or more subsamples or is positive for *L. mono* (collectively, "positive food samples"), then Defendants must immediately

cease production and notify FDA that production has ceased. Defendants shall also destroy, at Defendants' expense, under FDA's supervision, and pursuant to a written destruction plan approved in writing by FDA, all positive food samples, as well as all food manufactured since the positive food samples were collected. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and 21 C.F.R. Part 110. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew. Defendants shall ensure that the results of all testing conducted pursuant to this paragraph are forwarded to FDA within two (2) business days after receipt by Defendants.

8. If Defendants terminate or alter in any way their service contract with the laboratory retained pursuant to paragraph 5(A), Defendants shall notify FDA within five (5) business days after such termination or alteration. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new laboratory to FDA within five (5) business days after such services contract is executed.

9. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the facility(ies) and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to

receiving, preparing, processing, packing, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) business days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) business days after providing a copy of this Decree to a prospective successor or assign.

11. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree. The costs of such activities shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $88.45 per hour and fraction thereof per representative for inspection or investigative work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per-day, per-representative for subsistence expenses, where necessary. In the event that the

standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

12. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, holding, and distributing any articles of food;

B. Recall all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with microorganisms or filth; and/or

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 11 of this Decree.

13. Any cessation of operations as described in paragraph 12(A) shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

14. If any Defendant fails to comply with the provisions of the Act, its implementing regulations, and/or this Decree, then Defendants shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000.00) for each day that Defendants fail to comply with this Decree; an additional sum of five hundred dollars ($500.00) in liquidated damages per day for each violation of the Act, its implementing regulations, and/or this Decree; and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

15. If any Defendant violates this Decree and is found in contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

16. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

17. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of this Decree to each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA within twenty (20) business days after the date of entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

18. Defendants shall prominently post a copy of this Decree in an employee common area at the facility(ies) within ten (10) business days after entry of this Decree and shall ensure that the Decree remains posted for a period of at least six (6) months.

19. Defendants shall, within ten (10) business days after entry of this Decree, hold a general meeting or series of smaller meetings for employees of the facility(ies), at which they shall describe the terms and obligations of this Decree.

20. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, heirs, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree,

Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) business days after each instance that any Defendant becomes associated with any such additional persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all person who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Defendants shall address all communications with FDA required under this Decree to Director, Detroit District Office, Food and Drug Administration, 300 River Place Drive, Suite 5900, Detroit, Michigan 48207, and shall reference this civil action by case name and civil action number in such communications.

22. This Court shall retain jurisdiction of this action and the parties hereto for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this _____ day of _____, 2015.

_____
HONORABLE AVERN COHN
United States District Judge

Entry consented to:

For Defendants

/s/ Fina Serra
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Individually and on behalf of
S. Serra Cheese Company

/s/ Stefano Serra
STEFANO SERRA
Individually and on behalf of
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