UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

Case No. 14-13077

v.

HON. AVERN COHN

S. SERRA CHEESE COMPANY,
a corporation,

and

FINA SERRA and STEFANO SERRA,
individuals,

Defendants.
_____/

DECISION AND ORDER GRANTING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT (Doc. 24)

I. INTRODUCTION

This is a case under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, et seq. Plaintiff United States of America (the "Government") is seeking an injunction under 21 U.S.C. § 332(a), against Defendants S. Serra Cheese Company, Fina Serra, and Stefano Serra (collectively "Serra"), against violating the Federal Food, Drug, and Cosmetic Act (the "Act"). The Government says that Serra continues to violate the Act by introducing and delivering for introduction into interstate commerce adulterated food, a violation of 21 U.S.C. § 331(a). In addition, the Government says that Serra is adulterating food while it is held for sale after shipment of one or more of its components in interstate commerce, a violation of 21 U.S.C. § 331(k).

Now before the Court is the Government's motion seeking summary judgment and entry of a permanent injunction (Doc. 24). For the reasons that follow, the Government's motion for summary judgment is GRANTED. Also, the Government is entitled to a permanent injunction, the text of which is still an open question.

II. BACKGROUND

A. Serra's History

Serra is a Michigan corporation that has operated for over 16 years. Serra prepares, processes, packs, holds, and distributes an assortment of ready-to-eat ("RTE") cheeses, including ricotta, provolone, mozzarella, and primo sale. Its products are manufactured in Serra's facility (the "facility") located in Clinton Township, Michigan. Fina and Stefano Serra are co-owners of Serra. Serra ships its cheeses to retail and wholesale customers located outside Michigan and receives ingredients used to make its cheeses from sources outside Michigan.

B. Listeria and E. Coli[1]

Listeria is a genus of bacteria found in soil and water and some animals, including cattle. Listeria can be present in raw milk and can live in food processing plants. Listeria innocua ("L. innocua") is one of the species of Listeria. Although L. innocua is not pathogenic, its presence in a food facility is an indicator of insanitary conditions because L. innocua is not a normal bacterial flora of milk. L. innocua is often found in environments that also support the growth of L. monocytogenes ("L. mono"), a pathogenic organism that poses an acute, life-threatening hazard to human health

[1] This section is taken from the Declaration of Dr. Obianuju N. Nsofor, Food Microbiologist for the Division of Dairy, Egg, and Meat Products within the Office of Food Safety at the Center for Food Safety and Applied Nutrition ("CFSAN"), United States Food and Drug Administration ("FDA"), Department of Health and Human Services (Doc. 25).

because it is the causal agent for the disease listeriosis. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and those with impaired immune systems, and the four most serious forms of listeriosis can result in meningitis and septicemia. Although the presence of L. innocua in a food facility will not necessarily cause the food prepared there to be contaminated with L. innocua or L. mono, the presence of L. innocua indicates insanitary conditions under which such food is prepared whereby it may be contaminated with filth or rendered injurious to health, because it indicates that other microorganisms, such as L. mono, are likely to survive and flourish in the same processing environment.

Escherichia coli ("E. coli") are a diverse group of bacteria that include pathogenic and non-pathogenic strains. Strains of pathogenic E. coli can cause disease in humans, and their presence in food poses a hazard to human health. Non-pathogenic strains of E. coli (e.g., generic, non-pathogenic E. coli) in food are not commonly associated with human illness, but are used as an indicator of insanitary conditions during processing or contamination with filth. E. coli are not inherently present in the milk of dairy animals, and their presence in milk or other dairy products indicates that the milk or dairy products were exposed either directly or indirectly to feces. Insanitary conditions, including poor employee hygiene practices, improperly sanitized utensils and equipment, and/or contaminated raw materials, may also be a source of E. coli in milk and other dairy products.

C. Violations Observed During FDA Inspections

1. January 2013 Inspection

Between January 8 and 23, 2013, investigators from the United States Food and Drug Administration (the "FDA") Detroit District Office conducted a comprehensive inspection of the facility (Doc. 1, ¶ 17; Doc. 26, Ex. 3, ¶ 5). The inspection revealed significant violations and resulted in the FDA issuing an eight-item List of Inspectional Observations, Form FDA-483, that included the following: (1) failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials, as required by 21 C.F.R. § 110.35(a); (2) failure to construct the facility in such a manner as to allow floors to be adequately cleaned and maintained, as required by 21 C.F.R. § 110.20(b)(4); and (3) failure to store raw materials in a manner that protects against contamination, as required by 21 C.F.R. § 110.80(a)(1) (Doc. 1, ¶ 17). FDA officers discussed the violations with Defendant Fina Serra (Doc. 26, Ex. 3, ¶ 6). Serra did not respond to the January 2013 Form FDA-483 (Doc. 1, ¶ 17).

2. June 2013 Warning Letter

In June 2013, the FDA issued a Warning Letter to Defendant Fina Serra that discussed the current good manufacturing ("cGMP") violations noted during the January 2013 inspection and advised that samples collected during the inspection revealed L. innocua in the facility and generic, non-pathogenic E.coli in cheeses (Doc. 26, Ex. 3A). Such findings are indicative of insanitary conditions in the facility. The Warning Letter emphasized the serious nature of the deficiencies and stated that it was Serra's responsibility to ensure that its products comply with the Act (Doc. 1, ¶ 18). The

Warning Letter further explained that failure to correct these conditions could result in additional regulatory action, including an injunction (Doc. 26, Ex. 3A). In response, Serra promised to correct the insanitary conditions described in the Warning Letter (Doc. 26, Ex. 3B & 3C).

3. November 2013 Inspection

Between October 22 and November 8, 2013, FDA investigators conducted a comprehensive follow up to the January 2013 inspection and June 2013 Warning Letter (Doc. 24, Ex. 1, ¶ 10). This inspection resulted in the issuance of a second FDA Warning Letter addressing significant cGMP violations at the facility similar to those observed previously. Id. The inspection revealed that Serra failed to implement effective corrections to remedy the insanitary conditions previously observed at the facility. Id. The Warning Letter included the following observations: (1) Serra failed to perform filling and assembling in a manner that protects food from being contaminated, in violation of 21 C.F.R. § 110.80(b)(13); (2) Serra failed to take effective measures to protect finished food from contamination by raw materials, as required by 21 C.F.R. § 110.80(b)(6); (3) Serra failed to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food contact surfaces, in violation of 21 C.F.R. § 110.35(a); (4) Serra failed to construct the facility in such a manner as to allow floors to be adequately cleaned and kept clean and in good repair, in violation of 21 C.F.R. § 110.20(b)(4); and (5) Serra failed to store raw materials in a manner that protects against contamination. (Id. at ¶¶ 10(A)-(E)).

As examples, FDA investigators observed the following violations:

- An employee dropped a piece of plastic wrapping on the processing room floor which was unclean and wet with milk, and without cleaning it, picked it up and wrapped RTE provolone cheese with it (Doc. 24, Ex. 1, ¶ 10(A)).
- An employee washed perforated plastic trays on the floor of the facility's processing room immediately before filling the trays with mozzarella cheese (Id.).
- Employees dumped raw milk on the floor in a high-traffic area of the processing room (Id. at ¶ 10(B)).
- An employee used a hose to clean a table in a manner that caused water from the table and floor to splatter onto RTE provolone cheese (Id. at ¶ 10(C)).
- The concrete floor in the manufacturing area of the facility was pitted and porous and some areas of the floor had layers of paint or sealant that were cracked, peeling, and chipped. Standing water was observed in all areas of the walk-in cooler (Id. at ¶ 10(D)).[2]

During the November inspection, FDA inspectors collected 71 samples from the facility and laboratory analyses found L. innocua throughout the facility, including in eleven locations in close proximity to food (Doc. 24, Ex. 1, ¶ 11). In addition, analysis of sample number 794150 found significant levels of generic, non-pathogenic E.coli in finished RTE primo sale cheese (Doc. 24, Ex. 1, ¶ 12).

[2] Uneven, pitted, and porous floors are difficult to clean and sanitize adequately and standing water on such floors can serve as niches or harborages for L. mono and other pathogens, in violation of 21 C.F.R. § 110.20(b)(4) (Doc. 24, Ex. 2, ¶10(D)).

The FDA issued a seven-item Form FDA-483 to Defendant Fina Serra at the close of the November 2013 inspection (Doc. 24, Ex. 1, ¶ 14). FDA Consumer Safety Officer Margaret Persich discussed the observations noted in the Form FDA-483 with Fina Serra and explained that the FDA might seek further regulatory action, including a permanent injunction. Id. Fina Serra responded to the November 2013 inspection in an undated letter to the FDA received on January 22, 2014, representing that actions had been and were being taken to correct the cGMP violations identified in the November 2013 inspection (Doc. 26, Ex. 3D).

4. March 2015 Sample Testing Results

On March 23, 2015, Serra submitted to the FDA documentation stating that it conducted certain chemical cleaning activities at the facility. As part of the submission, Serra provided analytical results of environmental samples it had collected at the facility on March 13, 2015 (Doc No. 25, ¶ 18). The results showed that, as of March 13, 2015, Listeria spp. was present at multiple locations in the facility's environment, including on the production floor. Id. The locations where Listeria spp. was detected on March 13, 2015 were: Cooler Room #1 Drain; Cooler Room #3 Drain by the Door; Production Small Drain; and Production Center Floor (Doc. 26, Ex. 2G).

On March 27, 2015, Serra submitted analytical results to the FDA stating that on March 25, 2015, it had collected and tested environmental samples from the specific locations from which it had collected environmental samples on March 13, 2015 and that had tested positive for Listeria spp. (Doc. No. 25, ¶ 19). Serra's analytical results showed that the environmental samples it had collected on March 25, 2015 were negative for Listeria spp. Id.

III. DISCUSSION

A. Summary Judgment

The standard for summary judgment is well known and is not repeated in detail. "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Ultimately a district court must determine whether the record as a whole presents a genuine issue of material fact drawing "all justifiable inferences in the light most favorable to the non-moving party." Hager v. Pike Cnty. Bd. of Ed., 286 F.3d 366, 370 (6th Cir. 2002).

B. Overview

The Government says that Serra has violated the Act, 21 U.S.C. § 331(a) and (k). Section 331(a) prohibits "the introduction or delivery for introduction into interstate commerce of any food…that is adulterated…" 21 U.S.C. § 331(a). Section 331(k) prohibits "the doing of any other act with respect to, a food…if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated…" 21 U.S.C. § 331(k). To establish these violations, the Government has the burden to establish that (1) Serra's products are "food" within the meaning of the Act; (2) that the food was "adulterated" as the FDCA defines that term; and (3) that the food moved in interstate commerce. United States v. Am. Mercantile Corp., 889 F. Supp. 2d 1058, 1071 (W.D. Tenn. 2012).

According to the Government, there is no genuine issue of material fact. The Government points out that neither party disputes whether Serra's products are "food" or if the product travels in interstate commerce (Doc 36, ¶¶ 6-7). Serra's Response to

the Motion for Summary Judgment focuses on whether or not its product is adulterated and whether the relief being sought is an appropriate remedy (Doc. 30). Because both Serra and the Government focus on the second element and admit the establishment of the first and third elements in their Joint Statement of Facts, the Court finds that there are no genuine issues of material fact regarding the first and third elements and will focus solely on the second element, as well.

C. "Adulterated" Food as Defined by the Act

A food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(4). This provision of the Act pertains solely to the conditions under which food is prepared, packaged, or held; it is not necessary to prove that the food itself actually contains filth or is injurious to health. To establish adulteration under 21 U.S.C. § 342(a)(4), the government need only show a reasonable probability that, because of the insanitary conditions under which food is prepared, packed, or held, food may have been rendered filthy or injurious to health. United States v. Wiesenfeld Warehouse Co., 376 U.S. 86, 90-91 (1964); Berger v. United States, 200 F.2d 818, 821 (8th Cir. 1952); United States v. Gel Spice Co., Inc., 601 F. Supp. 1205, 1211 (E.D.N.Y. 1984). Proof of actual contamination is not required. United States v. Gel Spice Co., 773 F.2d 427, 429 (2nd Cir. 1985); United States v. King's Trading, Inc., 724 F.2d 631, 632 (8th Cir. 1983). "Even so, proof of actual contamination is prima facie evidence that the food has been held under insanitary conditions." Am. Mercantile Corp., 889 F. Supp. at 1076. Similarly, "the existence of insanitary conditions adjacent to food will create a reasonable possibility that the food

may become contaminated." Id. To prevent insanitary conditions that render their products adulterated, Serra must comply with the Act's cGMP regulations, 21 C.F.R. Part 110. The question of insanitary conditions is determined from the totality of the circumstances. Am. Mercantile Corp., 889 F. Supp. 2d at 1076.

D. Analysis

The facts of record establish that Serra's product is adulterated under 21 U.S.C. § 342(a)(4). The FDA's inspections of the facility, the numerous product sample results collected by the FDA, and Serra's own positive sample analyses all demonstrate that Serra repeatedly introduced adulterated food into interstate commerce and caused food to become adulterated while held for sale after shipment in interstate commerce. Serra proffers several arguments for why the Government's summary judgment should be denied. Serra's arguments are without merit as the Court will discuss below.

1. Findings from FDA Inspections Establish Violation of the Act's cGMPs

As noted supra, the Government has proffered multiple examples of Serra's violations of the Act's cGMPs, including but not limited to: Serra's failure to perform filling and assembling in a manner that protects food from becoming contaminated, in violation of 21 C.F.R. § 110.80(b)(13); Serra's failure to take effective measures to protect finished food from contamination by raw materials, such as raw, unpasteurized milk, in violation of 21 C.F.R. § 110.80(b)(6); Serra's repeated failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food and food contact surfaces, in violation of 21 C.F.R. § 110.35(a); etc.

In response, Serra says that the inspections alluded to in the Government's Complaint were conducted in 2013 and the necessary refurbishments and improvements to address the violations have been accomplished since then (Def. Resp. to Pl. Motion for Summ. Judgment, Doc. 30 at 12). This argument lacks merit. Aside from the assertions in its brief, Serra has not established proof of the assertions. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986)(non-moving party "must do more than simply show that there is some metaphysical doubt as to material facts…[and] come forward with specific facts showing that there is a genuine issue for trial"). Therefore, this argument fails.

Further, Serra argues that it is "highly questionable" whether the Government's observations actually constitute a finding of "filth" as required by the Act. This argument lacks merit. Also, actual contamination is not required – only reasonable possibility. For example, Serra says that the fact that a FDA representative observed an employee placing plastic wrap that fell on the floor onto cheese without cleaning the wrap does not mean that the cheese was actually put out into the marketplace (Doc. 30 at 14). However, there is a reasonable possibility that the cheese was put out into the marketplace; that is enough.

2. Sickness is Not a Required Element

Serra also says that it has not violated the Act because no one has reported sickness from eating Serra products (Doc. 30 at 8).This argument is also without merit. Actual contamination is not an element of adulteration under 21 U.S.C. § 342(a)(4). Food is adulterated simply if it has been held under insanitary conditions whereby it may

have become contaminated with filth or whereby it may have been rendered injurious to health. Id. Actual contamination is not required. King's Trading, Inc., 724 F.2d at 632.

3. Reasonable Possibility of Contamination is Sufficient – Actual Contamination is Not Required

Serra says that because the FDA did not find pathogenic L. mono. and E. coli contamination at the facility and because Serra only uses pasteurized milk for its cheese products, the food produced at the facility is not adulterated. (Doc. 30 at 7-8). This argument is without merit. The Government is not required to show actual contamination or injury under 21 U.S.C. § 342(a)(4). Food is "adulterated" simply if it has been held under insanitary conditions whereby there is a reasonable possibility for it to become contaminated with filth. Serra mistakenly bases its argument against adulteration on the fact that the samples taken showed non-pathogenic L. innocua and E. coli. (Doc. 30 at 7-8). However, the Government simply needs to show a reasonable possibility of contamination. Based on the observations listed supra of the insanitary conditions in the facility in conjunction with the test results finding L. innocua throughout the facility and generic E. coli in Serra's finished cheeses in samples taken from both the January 2013 and the November 2013 inspections, the Government has met its burden.

4. Source of Contaminants –Whether the Cheese or Added Ingredients – is Not the Issue

Serra argues that it is uncertain whether the L. innocua and E. coli were found on account of the cheese itself or contaminated ingredients added to the cheese (Doc. 30 at 14). This argument lacks merit. First, as noted above, the key inquiry to determine adulteration is not actual contamination but rather reasonable possibility of

contamination. The Government has established the requisite reasonable possibility. Further, Serra cannot argue that the finished product is not contaminated simply because the cheese it produced is clean and only the added ingredients are contaminated. Contaminants in a finished product produce a contaminated product – whether the contamination is from the cheese or the added ingredients.

IV. Injunctive Relief

A.

In determining whether to grant the Government's requested relief under 21 U.S.C. § 332(a), the Court does not need to consider whether there is an adequate legal remedy or irreparable injury. U.S. v. City of Painesville, Ohio, 644 F.2d 1186, 1193-94 (6th Cir. 1981); U.S. v. Edward Rose & Sons, 246 F. Supp. 2d 744, 753 (E.D. Mich. 2003). Because this is a Congressional Act to protect the public health, the Government only needs to establish that Serra violated the statute and there is some cognizable danger of recurrent violation. Edward Rose & Sons, 246 F. Supp. at 753. The Court considers several factors to determine the likelihood of future violations including, but not limited to, (1) the isolated or repeated nature of the violations, (2) the defendant's recognition of the wrongful nature of his conduct, and/or (3) the likelihood that the defendant's occupation will present opportunities for future violations. Id. at 753-54.

Serra defends against an injunction because it says the Government relies on outdated test results and ignores recent improvements to the facility. The argument has no merit. The Government has established the violations of the Act as described above. The Government is entitled to injunctive relief because Serra repeatedly violated the Act

despite the FDA's repeated warnings and Serra's assurances of improvements. Further, many of the improvements listed in Serra's Response to the Government's Motion for Summary Judgment were not instituted until February 2015 – six months after the filing of the Government's complaint (Doc. 30 at 12). Similarly, samples taken from the facility as recently as March 13, 2015 show the presence of Listeria spp. in multiple locations within the facility, including on the production floor (Obianuju Dec., Doc. 25, ¶ 18). This indicates that the changes Serra has implemented have not been sufficient to cure the insanitary conditions. The fact that samples taken on March 25, 2015 failed to detect Listeria does not establish a state of general cleanliness in the facility overall.

Even assuming that Serra is now compliant with the Act, the cessation of illegal conduct after litigation has commenced is not a reason to deny the Government the injunction it seeks. Once a violation of the Act is established, the Court has an obligation "to protect the public from a continuation of the harmful and unlawful activities. A trial court's wide discretion in fashioning remedies is not to be exercised to deny relief altogether by lightly inferring an abandonment of the unlawful activities from a cessation which seems timed to anticipate suit." U.S. v. Parke, Davis & Co., 362 U.S. 29, 48 (1960).

B.

The particular language of the injunction is yet to be decided. The Court is not disposed to immediately close the facility; the fact that it has continued to operate during the pendency of the case is of significance. Rather, the Government shall submit the form of injunction it believes appropriate within five business days. Serra shall respond within five business days. The Court will hold a conference with the parties on

November 5, 2015. If the language of the injunction is not resolved at the conference, the Court will hold a formal hearing on November 6, 2015.

V. CONCLUSION

For the reasons stated above, the Government's motion for summary judgment is GRANTED. The Court shall proceed as above described.

SO ORDERED.

s/Avern Cohn
AVERN COHN
UNITED STATES DISTRICT JUDGE

Dated: October 20, 2015
Detroit, Michigan