

The Honorable Benjamin H. Settle

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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

United States of America,

Plaintiff,

v.

Undetermined quantities of an article of food, cheese,
labeled in part,

“*** ESTRELLA FAMILY CREAMERY ***
Red Darla ***”

and

all other articles of food, cheese, in any size and type of
container, including in-process and finished products,
labeled or unlabeled, which are held anywhere on the
premises of Estrella Family Creamery, 659 Wynoochee
Valley Road, Montesano, Washington,

Defendants in rem,

and

ESTRELLA FAMILY CREAMERY, LLC,
a corporation, KELLI M. ESTRELLA,
and ANTHONY M. ESTRELLA,
individuals,

Defendants.

No. C10-5772-BHS

PLAINTIFF’S MOTION FOR
SUMMARY JUDGMENT

NOTE ON MOTION CALENDAR:
SEPTEMBER 7, 2012

NOW COMES Plaintiff, the United States of America, by and through Jenny A. Durkan, United States Attorney for the Western District of Washington, and Assistant United States Attorney, David R. East, and hereby moves this Court for (1) summary judgment pursuant to Rule 56 of the Federal Rules of

1 Civil Procedure; (2) condemnation of the seized articles of food pursuant to 21 U.S.C. § 334(a); and (3)
2 injunctive relief pursuant to 21 U.S.C. § 332(a) and this Court's inherent equitable powers.

3 I. INTRODUCTION

4 The United States Food and Drug Administration ("FDA") is a federal agency responsible for the
5 safety of food that moves in interstate commerce. As part of its mission, FDA inspects food
6 manufacturers to determine whether they comply with the laws and regulations designed to protect
7 public health. When their cheese-making business is fully operational, the Estrella Family Creamery
8 (the "Creamery"), Kelli M. Estrella, and Anthony M. Estrella (collectively, "Defendants") manufacture,
9 process, pack, and hold cheese, and distribute it in interstate commerce.

10 FDA and the Washington State Department of Agriculture ("WSDA") have inspected Defendants'
11 facility in Montesano, Washington, numerous times and have found *Listeria monocytogenes* ("*L.*
12 *mono*"), a dangerous pathogenic organism, in the facility's environment and in samples of Defendants'
13 finished cheese. On three separate occasions between August and October 2010, FDA investigators also
14 observed numerous violations of the current good manufacturing practice requirements for food
15 ("cGMP"), 21 C.F.R. Part 110, at the Creamery. Due to these violative practices and conditions, food
16 products prepared, packed, or held in Defendants' facility are adulterated under the Federal Food, Drug,
17 and Cosmetic Act ("FDCA" or the "Act"), 21 U.S.C. § 342(a)(4), because they have been held under
18 insanitary conditions whereby they may have been contaminated with filth, or whereby they may have
19 been rendered injurious to health. *See* 21 C.F.R. § 110.5(a). The government initiated this action to
20 seize and condemn the seized articles of food ("Defendants *in rem*"). The United States subsequently
21 amended its complaint to enjoin Defendants from producing and distributing adulterated food.

22 There is no genuine dispute as to any material fact concerning Defendants' adulteration of
23 cheese. Rather, the undisputed facts make clear that conditions at the Creamery were insanitary, and that
24 cheese manufactured there may have been contaminated with filth or rendered injurious to health. Thus,
25 (1) Defendants have adulterated articles of food that have traveled in interstate commerce, including
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1 Defendants *in rem*; (2) an order of condemnation of the Defendants *in rem*¹ is appropriate; and (3) court-
 2 ordered injunctive relief is necessary to ensure that in the event that Defendants re-engage in interstate
 3 activities, they comply with the FDCA. For these reasons, and as discussed more fully below, the United
 4 States respectfully requests that the Court grant this Motion for Summary Judgment and enter the
 5 Government's proposed Order of Condemnation and Permanent Injunction (filed herewith).

6 In support of its motion, the government submits the declarations (and exhibits attached thereto) of
 7 Charles M. Breen, Director, Seattle District Office, FDA ("Breen Decl."); Scott W. Fox, ("Fox Decl.");
 8 and Obianuju N. Nsofor, Dairy Food Microbiologist, Center for Food Safety and Nutrition, FDA
 9 ("Nsofor Decl.").

10 II. BACKGROUND

11 A. History of the Action

12 The government filed its initial complaint in this *in rem* seizure action on October 21, 2010,
 13 seeking seizure and condemnation of the Defendants *in rem*. See Dkt. 1 ("Initial Complaint"). The
 14 government's Initial Complaint alleged that the Defendants *in rem* were adulterated under the FDCA, 21
 15 U.S.C. § 342(a)(4), because they were prepared, packed, or held under insanitary conditions whereby
 16 they may have become contaminated with filth, or whereby they may have been rendered injurious to
 17 health. See generally *id.*

18 Pursuant to a Warrant of Arrest *In Rem* ("Warrant"), Dkt. 4, issued by this Court on or about
 19 October 21, 2010, the United States Marshal for this District seized the Defendants *in rem* on October
 20 21, 2010. Dkt. 27 ("Amended Compl.") ¶ 3; Dkt. 28 ("Ans. to Amend. Compl.") ¶ 3. Defendants filed a
 21 claim for the seized articles on December 14, 2010. Dkt. 10.

22 On September 30, 2011, the United States requested leave to amend the complaint to add
 23 individual and corporate defendants and to seek relief to enjoin Defendants' violative behavior. See Dkt.
 24 19. This Court granted the United States' motion on December 1, 2011, Dkt. 25, and the government
 25 filed its Amended Complaint on January 6, 2012. Dkt. 27. Defendants filed an answer to the
 26 government's Amended Complaint on January 26, 2012. Dkt. 28.

27
 28 ¹ As explained below, the fact that Defendants represent that they have unilaterally, and without
 Court approval, destroyed the Defendants *in rem* does not diminish the factual or legal basis for an order
 of condemnation.

1 B. Statement of Facts

2 1. Defendants

3 The Creamery is a limited liability corporation incorporated in the state of Washington. Amended
4 Compl. ¶ 9; Ans. to Amend. Compl. ¶ 9. It is family operated and co-owned by Defendant Kelli Estrella
5 and her husband, Defendant Anthony Estrella. Amend. Compl. ¶¶ 10, 11; Ans. to Amend. Compl.
6 ¶¶ 10, 11; Breen Decl. ¶ 6. Defendants' cheese manufacturing facility, which is located on the same
7 property as their residence at 659 Wynoochee Valley Road, Montesano, Washington ("Defendants'
8 facility" or "Montesano facility"), is within the jurisdiction of this Court. Amended Compl. ¶ 9; Ans. to
9 Amend. Compl. ¶ 9.

10 When its cheese-making business was fully operational, the Creamery received components of
11 cheese in interstate commerce and then prepared, processed, packed, held for sale, and distributed a
12 variety of cheese products to interstate customers and customers within Washington State. Amended
13 Compl. ¶¶ 12, 13; Ans. to Amend. Compl. ¶¶ 12, 13; Breen Decl. ¶ 7. Although Defendants report that
14 they have ceased operations in response to this action, Defendant Kelli Estrella has stated that "it is
15 [their] desire to make cheese again." Affidavit of Kelli Estrella in Opposition to Plaintiff's Motion to
16 Amend Complaint, Dkt. 22-1 ("Estrella Aff.") ¶ 57.²

17 Defendants Kelli and Anthony Estrella have represented to FDA that they share responsibility,
18 oversight, and ultimate authority over the Creamery's major business decisions. Amended Compl.
19 ¶¶ 10, 11; Ans. to Amended Compl. ¶ 10; Breen Decl. ¶ 6. Kelli Estrella has identified herself as
20 responsible for the Creamery's cheese manufacturing and sanitation practices. Amended Compl. ¶ 10;
21 Ans. to Amend. Compl. ¶ 10. Anthony Estrella has identified himself to FDA investigators as being
22 responsible for the Creamery's facility maintenance, dairy production, and farm operations. Breen Decl.
23

24 ² Although Defendants' counsel has represented to the government that Defendants intend to resume
25 cheesemaking, but engage in exclusively intrastate operations, the government – in light of Defendants'
26 violative history and the government's obligations to protect the public – cannot simply take Defendants
27 at their word. Indeed, because Defendants have previously relied on components obtained through
28 interstate commerce, and they have sold their cheese to customers outside Washington State, the
government is skeptical that Defendants will be able to operate a wholly intrastate cheesemaking
business. Thus, in order to protect the public against the possibility that Defendants re-engage in
interstate cheesemaking operations, the government's proposed order authorizes FDA to confirm that
Defendants are not engaging in any interstate activities, and enumerates certain conditions that would
apply in the event that Defendants resume interstate activities governed by the FDCA.

¶ 6. When their cheese-making business was fully operational, both individual Defendants performed their duties at the Montesano facility. Amended Compl. ¶¶ 10-11; Ans. to Amend. Compl. ¶ 10; Breen Decl. ¶ 6.

2. *L. mono*

a. The Health Risks Associated with *L. mono*

L. mono is a pathogenic organism that poses an acute, life-threatening hazard to human health, because it is the causal agent for the disease listeriosis. Nsofor Decl. ¶ 5. Serious illness often occurs in vulnerable populations, such as infants, the elderly, and people whose immune systems are impaired by disease or medications. *Id.* The mortality rate for these high-risk individuals is about twenty percent. *Id.* In pregnant women, listeriosis can cause abortion and/or severe septicemia (the presence of bacteria in the bloodstream) in the newborn. *Id.* Other possible complications from the disease include pneumonia and endocarditis. *Id.* Unlike many other foodborne microbes, *L. mono* bacteria are capable of multiplying even at refrigeration temperatures. *Id.* An outbreak of listeriosis caused by *L. mono* in cantaloupes during a recent outbreak in the United States resulted in 30 confirmed deaths and 142 hospitalizations. *Id.* Thus, *L. mono* in ready-to-eat foods is a significant public health risk.

b. Controlling for the *L. mono* Food Safety Hazard

L. mono can be controlled if food facilities engage in good manufacturing practice. Nsofor Decl. ¶ 6. Properly cleaning and sanitizing equipment and facilities are necessary to ensure that *L. mono* does not find niches in which to reside and proliferate. *Id.* Testing finished products alone is insufficient for assessing and verifying control of *L. mono*. *Id.* Rather, an environmental sampling program is both more appropriate and cost-effective. *Id.* Adequate cleaning and sanitation procedures are particularly important in facilities where a persistent strain of *L. mono* has been found. *Id.*

3. Defendants' Conduct and Notice of Violations

Defendants have prepared, packed, and held cheese they manufacture under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. When notified by regulatory authorities of food manufacturing violations that could threaten the public health, Defendants refused to cooperate with FDA (Breen Decl. ¶ 12), and, as described below and in the Estrella Affidavit (Dkt. 22-1), even after the goods were seized and in the jurisdiction of this

1 Court, they defied this Court's authority by destroying articles that were under its control. Estrella Aff.
2 ¶ 45.

3 On February 1, 9, and March 1, 2010, the WSDA collected finished cheese products, salt brine
4 solution, rennet,³ and environmental samples at the Creamery. Affidavit of Lisa Elrand, Dkt. 1 (pp.6-9)
5 ("Elrand Aff.") ¶ 5; Breen Decl. ¶ 13; Estrella Aff. ¶¶ 28-29. The state's laboratory analyses of the
6 samples collected from the Creamery revealed the presence of *L. mono* in the finished cheese, in the salt
7 brine solution, and throughout the Creamery's production and storage environments. Elrand Aff. ¶ 5;
8 Breen Decl. ¶ 13, Ex. B-7⁴; *see also* Estrella Aff. ¶¶ 28-29. In response to these findings, Defendants
9 recalled several cheese products on February 10, 15, and March 5, 2010. Elrand Aff. ¶ 5; Breen Decl.
10 ¶ 13; Estrella Aff. ¶ 31.

11 From August 2-4, 2010, FDA inspected the Creamery ("August 2010 Inspection") and collected
12 several environmental samples and finished cheese products. Elrand Aff. ¶ 6; Breen Decl. ¶ 14, Exs. B-
13 8, B-9. Several environmental samples from the cheese room and one sample from Cave 3 tested
14 positive for the presence of *L. mono*. *Id.* During this inspection, the firm also disclosed to FDA
15 investigators that it tested its products for *Listeria* between March and May 2010, and that one sample
16 tested positive for *L. mono*. Elrand Aff. ¶ 7; Breen Decl. ¶ 14. Although FDA investigators did not
17 issue a List of Inspectional Observations, Form FDA-483 ("Form FDA-483") at the close of the August
18 2010 inspection, they did orally report to Defendants several violative conditions observed, including:
19 (1) tape and peeling paint on the handles of the cheese press table; (2) rust on hanging weights on the
20 cheese press; (3) flying insects and a spider in the milk room vestibule and flies in the cheese processing
21 room; (4) uncovered whey collection tank; (5) old milk residue on the wall under the whey discharge
22 sink; and (6) untreated, rough-cut wooden shelves covered with product residue in cheese aging areas.
23 Breen Decl. ¶ 15, Ex. B-10.

24 FDA followed up on the positive *L. mono* results by returning to the Creamery on August 16, 2010.
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26 ³ All of Defendants' cheese is made with rennet, which Defendants purchased from a company
27 located in Wisconsin. Amended Compl. ¶ 13; Ans. to Amended Compl. ¶ 13. Rennet contains enzymes
28 that cause milk to curdle. It is commonly used to manufacture cheese. Breen Decl. ¶ 7 n.1.

⁴ Exhibits B-1 through B-12 are attached to the Breen Decl.; Exhibits C-1 and C-2 are attached to the
Fox Decl.

1 Breen Decl. ¶ 16. During that visit, FDA investigators collected a sample of Caldwell Crik Chevrette
2 cheese made on April 27, 2010. Elrand Aff. ¶ 8; Breen Decl. ¶ 16. Kelli Estrella asserted that the
3 product was part of the Creamery's commercial inventory of product ready to be distributed. *Id.* That
4 sample also tested positive for *L. mono*. *Id.*

5 Analysis using Pulsed Field Gel Electrophoresis ("PFGE") showed that *L. mono* isolates obtained
6 from FDA environmental samples collected on August 2-3, 2010, FDA finished product sample
7 collected on August 16, 2010, and finished product samples collected by the WSDA in February-May
8 2010 had indistinguishable characteristics (i.e., the same genetic fingerprint). Nsofor Decl. ¶ 11. When
9 a PFGE pattern of an isolate is indistinguishable from the pattern of another isolate from a common
10 source (i.e., from the facility and the products therein), it is highly likely that the two isolates are the
11 same strain of *L. mono*, and that *L. mono* may have been transported throughout the facility and
12 established niche areas. *Id.* The presence of a persistent strain of *L. mono* in the facility over time is
13 significant, because it demonstrates that sanitation efforts were inadequate to eliminate this pathogen.
14 *Id.*

15 FDA and WSDA conducted the most recent inspection of the Creamery from September 1-10,
16 2010 ("September 2010 Inspection"). Elrand Aff. ¶ 10; Breen Decl. ¶ 9. During this inspection, the
17 Creamery provided FDA and WSDA with laboratory reports revealing that cheese that the Creamery
18 apparently produced on January 29, June 15, 26, and 29, and July 8, 2010, had all tested positive for *L.*
19 *mono*. Breen Decl. ¶ 11; *see also* Elrand Aff. ¶ 10. Investigators also found three paper-wrapped
20 cheeses labeled "FDA sample, do not sell" stacked together on an aging shelf; these cheeses appeared to
21 be the three remaining cheeses from the lot sampled by FDA on August 16, 2010, that tested positive for
22 *L. mono*. *Id.* Defendants had previously informed FDA that those wheels of cheese had been destroyed.
23 *Id.*

24 During the September 2010 Inspection, FDA investigators observed several violations of cGMP at
25 the Creamery. Breen Decl. ¶ 9. At the close of the inspection, FDA investigators issued a Form
26 FDA-483 to Defendants, outlining ten observed cGMP violations. *Id.* ¶ 10. Those violations included,
27 among others: failure to manufacture and store foods under conditions and controls necessary to
28 minimize the potential for growth of microorganisms and contamination, as required by 21 C.F.R.

1 § 110.80(b)(2); failure to take necessary precautions to protect against contamination of food and food-
 2 contact surfaces with microorganisms or foreign substances, as required by 21 C.F.R. § 110.10(b)(9);
 3 workers' failure to wash their hands thoroughly in an adequate hand-washing facility after each absence
 4 from the work station and at any time their hands may have become soiled or contaminated, as required
 5 by 21 C.F.R. § 110.10(b)(3); failure to wear outer garments suitable to the operation in a manner that
 6 protects against the contamination of food and food packaging materials, as required by 21 C.F.R.
 7 § 110.10(b)(1); failure to take effective measures to protect against the inclusion of metal or other
 8 extraneous material in food, as required by 21 C.F.R. § 110.80(b)(8); failure to have equipment allowing
 9 for adequate cleaning,⁵ as required by 21 C.F.R. § 110.40(a); failure to take effective measures to
 10 exclude pests from the processing areas and to protect against food contamination by pests, as required
 11 by 21 C.F.R. § 110.35(c); and failure to wear hair restraints where appropriate, as required by 21 C.F.R.
 12 § 110.10(b)(6). *Id.* ¶ 10, Exs. B-3, B-4.

13 On September 3, 2010, FDA requested that Defendants recall all of their cheese products. Elrand
 14 Aff. ¶ 12; Breen Decl. ¶ 12; *see also* Estrella Aff. ¶ 35-36. Defendants declined. *Id.* The following day,
 15 FDA issued a news release advising consumers that consuming any Estrella Creamery cheeses could put
 16 them at risk for *L. mono* related illnesses. Elrand Aff. ¶ 13; Breen Decl. ¶ 12, Ex. B-6.

17 On October 21, 2010, the United States filed its Initial Complaint in this matter, seeking seizure
 18 and condemnation of articles of cheese held at Defendants' facility. *See* Initial Complaint (Dkt. 1). On
 19 the same day, officials from the United States Marshals Service seized the Defendants *in rem* in place at
 20 the Creamery, and placed "Warning" and "No Trespassing" signs on the doors of the buildings
 21 containing the Defendants *in rem*. Fox Decl. ¶ 5. Those notices stated that Defendants were prohibited
 22 from "attempting to remove" or "in any way interfering with" the seized property. *Id.* The United States
 23 Marshals Service also served Defendants with notice of the seizure action, including the Warrant and all
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26 ⁵ In her affidavit, Kelli Estrella admits that the Creamery uses rough cut wooden shelving and that the
 27 wooden shelving can sustain bacterial growth. Estrella Aff. ¶ 16. She said that she resists changing the
 28 shelves, preferring instead "to follow time honored wisdom rather than conventional industrial food
 practices." *Id.* ¶ 53. But, the use of rough-cut, undressed wooden shelves to store and age cheese is an
 insanitary condition and a violation of cGMP, 21 C.F.R. § 110.40(a), because it is impossible to clean
 such shelves adequately to prevent bacterial growth. Nsofor Decl. ¶¶ 18-19.

1 documents filed by the government in support of the seizure. *Id.*⁶

2 After the seizure, Defendant Kelli Estrella acknowledged that Defendants were prohibited from
3 moving the seized items: “[w]e were told that if we take any cheese out, I presume even for our own
4 consumption, that we risk imprisonment.” The Estrella Family,
5 http://www.youtube.com/watch?feature=player_embedded&v=P3ki_vnlOFY (at about 04:30) (last
6 visited August 13, 2012); Fox Decl. ¶ 11.

7 Notwithstanding full knowledge of the status of the seized articles, Defendants admit in sworn
8 affidavits that they destroyed all of the cheese that had been seized under this Court’s order. *See Estrella*
9 *Aff.* at ¶¶ 45-46; Dkt. 22-2 at ¶ 8.

10 Although Defendants have represented that they are not presently distributing cheese, FDA has not
11 confirmed that fact, and, even if true, Defendants have represented that they intend to resume operations
12 in the future. *See Estrella Aff.* ¶ 57 (“It is our desire to make cheese again, but who will protect us from
13 FDA?”). Because Defendants’ actions to date demonstrate that they will not voluntarily comply with the
14 law or this Court’s authority, the government respectfully submits that an injunction is necessary to
15 protect the public against potential future violations.

16 III. LEGAL STANDARD

17 Under the Federal Rules, “[t]he court shall grant summary judgment if the movant shows
18 that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter
19 of law.” Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting the
20 language of former Rule 56©, whereby “summary judgment is proper ‘if . . . there is no genuine issue as
21 to any material fact’”). “[T]he mere existence of *some* alleged factual dispute between the parties will
22 not defeat an otherwise properly supported motion for summary judgment; the requirement is that there
23 be no *genuine* issue of *material* fact.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986)
24 (emphasis in original). “An issue is ‘genuine’ only if there is a sufficient evidentiary basis on which a

25
26 ⁶ During the seizure, FDA investigators observed and documented several additional insanitary
27 conditions that may render Defendants’ cheese contaminated with filth or injurious to health.
28 Specifically, FDA investigators observed small insects on and around cheese in the Beulah Cave. Fox
Decl. ¶ 9. They also observed spider webs throughout the cheese racks and on two of Beulah Cave’s
walls. *Id.* There were soiled rags, paper debris, and gloves scattered on the shelves among the stored
cheese in that cave. *Id.*; Fox Decl., Ex. C-2 at 1. In Cave 1, FDA investigators observed soiled rags on a
shelf between cheese products. Fox Decl. ¶ 7, Ex. C-2 at 3-4.

1 reasonable fact finder could find for the nonmoving party, and a dispute is ‘material’ only if it could
 2 affect the outcome of the suit under the governing law.” *In re Barboza*, 545 F.3d 702, 707 (9th Cir.
 3 2008) (citing *Anderson*, 477 U.S. at 248). However, “[i]f the evidence is merely colorable . . . , or is not
 4 significantly probative . . . , summary judgment may be granted.” *Anderson*, 477 U.S. at 249–50
 5 (citations omitted). “The nonmoving party may not merely state that it will discredit the moving party’s
 6 evidence at trial, in the hopes that evidence can be developed at trial to support the claim.” *McCarthy v.*
 7 *Farwell*, 2012 WL 10390, *2 (W.D. Wash. Jan. 3, 2012) (Settle, J.) (citing *T.W. Elec. Serv., Inc. v. Pac.*
 8 *Elec. Contractors Ass’n*, 809 F.2d 626, 630 (9th Cir. 1987)).

9 IV. ARGUMENT

10 Summary judgment is appropriate in this case because there is no genuine dispute as to any fact
 11 material to any of the government’s claims enumerated in the Amended Complaint. FDA’s inspections
 12 of the Creamery, the numerous environmental and finished product sample results collected by FDA and
 13 WSDA, and Defendants’ own positive sample analyses all demonstrate that Defendants repeatedly
 14 introduced adulterated food into interstate commerce and caused food, including the Defendants *in rem*,
 15 to become adulterated while held for sale after shipment in interstate commerce. In short, the relief
 16 sought by the government is necessary and warranted because Defendants have violated the Act and, in
 17 light of their prior violative conduct, they are likely to violate the Act again in the future if not enjoined.

18 A. A Judgment of Condemnation Is Appropriate

19 Condemnation of the Defendants *in rem* is appropriate in this case. Under the Act,

20 [a]ny article of food . . . that is adulterated . . . when introduced into or while in interstate
 21 commerce or while held for sale (whether or not the first sale) after shipment in interstate
 22 commerce . . . shall be liable to be proceeded against while in interstate commerce, or at
 any time thereafter, on libel of information and condemned in any district court of the
 United States . . . within the jurisdiction of which the article is found.

23 21 U.S.C. § 334(a). Further, the Act provides:

24 When a decree of condemnation is entered against the article, court costs and fees, and
 25 storage and other proper expenses, shall be awarded against the person, if any,
 intervening as the claimant of the article.

26 21 U.S.C. § 334(e). Defendants *in rem* are subject to condemnation because they were (1) articles of
 27 food (2) that were adulterated (3) while held for sale after shipment of one or more of their ingredients in
 28 interstate commerce, and, pursuant to § 334(e), the United States should be granted court costs and

1 proper expenses for its role in carrying out the seizure.

2 1. Adulteration under the FDCA

3 The Defendants *in rem* were adulterated under 21 U.S.C. § 342(a)(4) because they were prepared,
 4 packed, and held in a Creamery environment in which *L. mono* was found and in which Defendants
 5 failed to comply with cGMP. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) “if it has
 6 been prepared, packed, or held under insanitary conditions whereby it may have become contaminated
 7 with filth or whereby it may have been rendered injurious to health.” This provision focuses solely on
 8 the conditions under which food is prepared, packed, or held. It is not necessary to prove that the food
 9 itself is contaminated or injurious to health. *See United States v. Rhody Dairy, LLC*, 812 F. Supp. 2d
 10 1239, 1242 (W.D. Wash. 2011); *see also United States v. Int’l Exterminator Corp.*, 294 F.2d 270, 271
 11 (5th Cir. 1961); *Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952). Courts have broadly
 12 construed this provision to prohibit any condition or practice that may render food injurious to health.
 13 *See United States v. Blue Ribbon Smoked Fish, Inc.*, 179 F. Supp. 2d 30, 44-45 (E.D.N.Y. 2001), *aff’d in*
 14 *relevant part*, 56 Fed. Appx. 542 (2nd Cir. 2003) (adulteration proved by showing a reasonable
 15 possibility that articles of food prepared, packed, or held under insanitary conditions may be injurious to
 16 health).

17 To establish adulteration under 21 U.S.C. § 342(a)(4), the government need only show a
 18 reasonable possibility that, because of insanitary conditions, the food may have been rendered injurious
 19 to health. *Rhody Dairy*, 812 F. Supp. 2d at 1242 (“The law is clear that § 342(a)(4) requires that the
 20 Government need only show a ‘reasonable possibility’ that conditions under which the food is ‘prepared,
 21 packed, or held’ may render the food injurious to health.”) (internal citation omitted); *see also Berger*,
 22 200 F.2d at 821; *Int’l Exterminator Corp.*, 294 F.2d at 271.

23 The regulations found at 21 C.F.R. Part 110 set forth the cGMP requirements for food
 24 manufacturing facilities, and apply in determining whether food is adulterated within the meaning of 21
 25 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 110.5(a)(2). If a manufacturer has not fully complied with cGMP,
 26 the food it produces is adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See id.*

27 a. Defendants’ Cheese Products Are Food within the Meaning of the Act

28 The Act defines “food” as “(1) articles used for food or drink for man or other animals . . . and (3)

1 articles used for components of any such article.” 21 U.S.C. § 321(f). Here, Defendants admit that
 2 “cheese is ‘food’ within the meaning of 21 U.S.C. § 321(f).” Amended Complaint ¶ 12; Ans. to Amend.
 3 Compl. ¶ 12; *see also United States v. Union Cheese Co.*, 902 F. Supp. 778, 785 (N. D. Ohio 1995).

4 b. Defendants in rem Were Held for Sale after Shipment in Interstate Commerce

5 Section 334(a) of Title 21 provides for the condemnation of adulterated articles of food “while held
 6 for sale . . . after shipment in interstate commerce.” Courts have interpreted the “held for sale”
 7 requirement broadly. *See Rhody Dairy*, 812 F. Supp. 2d at 1244; *United States v. Evers*, 643 F.2d 1043,
 8 1050 (5th Cir. 1981) (doctors holding drugs for use in their practice hold the drugs for sale within the
 9 meaning of the Act); *see also United States v. Diapulse Corp. of Am.*, 514 F.2d 1097, 1098 (2d Cir.
 10 1975) (devices, used in the treatment of patients, may properly be considered “held for sale” within the
 11 meaning of the Act) (internal citations omitted); *United States v. Articles of Animal Drug Containing*
 12 *Diethylstilbestrol*, 528 F. Supp. 202, 205 (D. Neb. 1981) (unapproved new animal drug is held for sale
 13 even while being held by distributor pending return to manufacturer); *but see United States v. Geborde*,
 14 278 F.3d 926, 931-32 (9th Cir. 2002) (in a criminal proceeding, homemade drugs distributed free of
 15 charge among friends were not “held for sale”). Here, it is undisputed that Defendants *in rem* were
 16 being “held for sale” because Defendants admit that they sell their cheese to the public for consumption.

17 The Act defines interstate commerce as “commerce between any State or Territory and any place
 18 outside thereof.” 21 U.S.C. § 321(b). “[T]he ‘shipment in interstate commerce’ requirement is satisfied
 19 even when only an ingredient is transported interstate.” *Baker v. United States*, 932 F.2d 813, 814 (9th
 20 Cir. 1991). Here, Defendants admit that they received rennet, an ingredient in all of Defendants’ cheese
 21 products, from a vendor in Wisconsin. Amended Complaint ¶ 13; Ans. to Amend. Compl. ¶ 13; *see*
 22 *Breen Decl.* ¶ 7.

23 Because Defendants received at least one ingredient of the Defendants *in rem* from outside the
 24 state of Washington, and the Defendants *in rem* were “held for sale” after shipment of such component
 25 in interstate commerce, Defendants *in rem* are liable to be condemned under 21 U.S.C. § 334(a).

26 c. Defendants in rem Were Prepared, Packed, and Held Under Insanitary
 27 Conditions Whereby They May Have Become Contaminated with Filth,
 28 or Whereby They May Have Been Rendered Injurious to Health

Defendants *in rem* are adulterated under 21 U.S.C. § 342(a)(4) in two ways. First, they are

1 adulterated because they have been prepared, packed, and held under insanitary conditions whereby they
 2 may have become contaminated with *L. mono*. Second, they are adulterated because Defendants' failure
 3 to comply with the cGMP requirements for foods caused insanitary conditions whereby the food may
 4 have become contaminated with filth or rendered injurious to health. *See* 21 C.F.R. Part 110.

5 i. Defendants *in rem* Are Adulterated Because They Are Manufactured in
 6 Conditions Whereby They May Have Become Contaminated with *L. mono*

7 Environmental and finished product samples collected from the Creamery by FDA, WSDA, and
 8 Defendants themselves show significant *L. mono* contamination in the Creamery's facilities.
 9 Environmental samples collected during WSDA's February 9, 2010, inspection and FDA's August 2010
 10 inspection from Defendants' storage areas and from the cheese processing area ("cheese room")
 11 revealed that *L. mono* was present in Defendants' food processing and storage environments. Breen
 12 Decl. ¶¶ 13, 14, Exs. B-7, B-8, B-9. Finished product samples collected by FDA on August 16, 2010; by
 13 WSDA in February and March 2010; and by Defendants on January 29, June 15, 26, and 29, and July 8,
 14 2010, all tested positive for *L. mono*. Breen Decl. ¶¶ 11, 13, 16, Exs. B-5, B-7, B-11.

15 Subsequent PFGE analysis showed that *L. mono* isolates obtained from FDA environmental
 16 samples collected on August 2-3, 2010, FDA finished product sample collected on August 16, 2010, and
 17 finished product samples collected by the WSDA in February-May 2010, revealed that it is highly likely
 18 that the isolates are the same strain of *L. mono*, and that *L. mono* may have been transported throughout
 19 the facility and established niche areas. Nsofor Decl. ¶ 11. This finding suggests that any cleaning that
 20 Defendants undertook between February and August 2010 was ineffective to eliminate that strain of *L.*
 21 *mono* from the Creamery. *See id.* ¶ 22.

22 As discussed in greater detail above, *L. mono* can cause death if ingested. *See* Section II(B)(2),
 23 *supra*. The persistent presence of such pathogenic bacteria in the Creamery's environment creates an
 24 insanitary condition whereby the Defendants *in rem* may have been rendered injurious to health. Nsofor
 25 Decl. ¶ 22. Thus, Defendants *in rem* are adulterated under 21 U.S.C. § 342(a)(4).

26 ii. Defendants *in rem* Were Adulterated Because
 27 Defendants' Manufacturing Operations Did Not Comply with cGMP

28 If a food manufacturer does not comply with cGMP, the food it produces is adulterated under 21
 U.S.C. § 342(a)(4). 21 C.F.R. § 110.5(a)(2). During the September 2010 inspection of the Creamery,

1 FDA investigators documented several deviations from cGMP. *See* Section II(B)(3)), *supra*; Breen
 2 Decl. ¶ 10; Elrand Aff. ¶ 11. Defendants' failure to comply with cGMP creates insanitary conditions
 3 whereby food processed at the Creamery may have become contaminated with filth or whereby it may
 4 have been rendered injurious to health, causing the Defendants *in rem* to be adulterated under the 21
 5 U.S.C. § 342(a)(4). *See* 21 C.F.R. § 110.5(a)(2).

6 2. A Judgment of Condemnation Is Appropriate Despite Defendants' Destruction of the Res

7 The relief that the government seeks is not merely the condemnation of the seized goods, but a
 8 condemnation determination that binds Defendants should they later decide to distribute goods like the
 9 ones seized. Because a judgment would be *res judicata*, this determination is critical to protect the
 10 public from adulterated goods like these in the future: "Any judgment condemning the seized devices
 11 will be *res judicata* against [claimant] and those in privity of contract with it in any subsequent litigation
 12 brought by the United States involving the same issues." *United States v. Various Articles of Device*
 13 *Identified in Attachment "A"*, 814 F. Supp. 31, 32 (E.D. Tenn. 1992) (internal citations omitted). *See*
 14 *also United States v. An Article of Food . . . "Schmidt's Blue Ribbon . . ."* Civ. No. 72-703-HM (D. Md.
 15 Jan. 25, 1974) (reported in Vincent A. Kleinfeld, et al., *Federal Food, Drug & Cosmetic Act 1969-1974*
 16 166, 168 (1976)) ("If . . . the Bakery is a party to a judgment on the merits favoring the Government,
 17 then the effect of *res judicata* will prevent a return to misbranding and the necessity of a second lengthy
 18 lawsuit by the Plaintiff.") (Attached hereto as Appendix A); *United States v. 14 105 Pound Bags, More*
 19 *or Less, Mineral Compound*, 118 F. Supp. 837, 839 (D. Idaho 1953); *United States v. 4 Cans, Etc.,*
 20 *Master Liquid*, 127 F. Supp. 243, 246 (N. D. Iowa 1955).

21 A key issue in the cases cited, as in this case, was whether the seized goods violated the Act. In
 22 reaching their decisions, the courts held prior judgment regarding violations to be *res judicata*.
 23 Although the courts acknowledged some differences in the products, the courts found that the cases were
 24 substantially similar and that the underlying issue therefore remained the same. Thus, a judgment of
 25 condemnation in this case could (if necessary) conserve taxpayer resources and promote judicial
 26 efficiency by preventing re-litigation of similar issues in the future.

27 3. The Government Should Be Compensated for Costs Incurred While Executing the Seizure

28 The Act provides that costs incurred in seizure and condemnation proceedings are to be awarded

1 against the claimants of the seized articles. 21 U.S.C. § 334(e). *See also Hipolite Egg Co. v. United*
 2 *States*, 220 U.S. 45, 59-60 (1911); *United States v. Articles of Drug . . . Penapar VK . . .*, 458 F. Supp.
 3 687, 689 (D. Md. 1978) (costs sought by plaintiff included court costs, cost of destruction, and cost of
 4 supervision of destruction). Accordingly, the government respectfully requests that the Court order
 5 Defendants to reimburse the government for the costs associated with United States Marshals' and FDA
 6 investigators' seizure of the Defendants *in rem* on October 21, 2010, as well as all court costs and fees
 7 and other proper expenses.

8 B. An Injunction Against Defendants Is Appropriate and Necessary

9 The Act grants federal courts power to issue injunctions to restrain violations of the Act. 21 U.S.C.
 10 § 332(a); *see also United States v. Organic Pastures Dairy Co.*, 708 F. Supp. 2d 1005, 1011 (E.D. Cal.
 11 2010). An injunction is appropriate in a situation such as this one, where Defendants violated the Act,
 12 rejected FDA's reasonable recall request, defied this Court's Order, and thus are likely to continue to
 13 violate the Act unless enjoined.

14 1. District Courts Have Jurisdiction to Enjoin Violations of the Act

15 The Act prohibits both the distribution in interstate commerce of food that is adulterated and any
 16 act that results in adulteration of an article of food that has traveled in interstate commerce. 21 U.S.C.
 17 § 331(a), (k). The Act's injunctive power should be exercised in light of its purpose to protect the public
 18 health, *see United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), and is
 19 appropriate when the government establishes that the defendant has violated the applicable statute and
 20 that there exists "some cognizable danger of recurrent violation." *United States v. W.T. Grant Co.*, 345
 21 U.S. 629, 633 (1953); *Rhody Dairy*, 812 F. Supp. 2d at 1245-46.

22 The probability of future violations may be inferred from past violations of the Act. *See United*
 23 *States v. Laerdal Mfg. Corp.*, 73 F.3d 852, 857 (9th Cir. 1995) (citing *S.E.C. v. Koracorp Indus., Inc.*,
 24 575 F.2d 692, 298 (9th Cir. 1978)); *Organic Pastures Dairy*, 708 F. Supp. 2d at 1012 (internal citations
 25 omitted). Once the government establishes the existence of the statutory violation, the burden shifts to
 26 Defendants to show that "there is no reasonable expectation that the wrong will be repeated." *W.T.*
 27 *Grant Co.*, 345 U.S. at 633 (internal citation and quotation marks omitted). Accordingly, "[a] district
 28 court may issue an injunction if it concludes that the injunction is necessary to prevent future violations."

1 *United States v. Articles of Drug*, 825 F.2d 1238, 1248 (8th Cir. 1987) (internal citation omitted).

2 Where, as here, the government seeks an injunction authorized by statute, the standard applicable
 3 to private litigants in equity does not apply. *See Rhody Dairy*, 812 F. Supp. 2d at 1245-46 (citing *United*
 4 *States v. City & County of San Francisco*, 310 U.S. 16, 30-31 (1940), *Biodiversity Legal Found. V.*
 5 *Badgley*, 309 F.3d 1166, 1177 (9th Cir. 2002)). The government does not need to prove irreparable
 6 harm because harm is presumed when the statute is violated. *United States v. Odessa Union Warehouse*
 7 *Co-op*, 833 F.2d 172, 176 (9th Cir. 1987) (internal citations omitted); *EEOC v. Cosmair, Inc., L'Oreal*
 8 *Hair Care Div.*, 821 F.2d 1085, 1090 (5th Cir. 1987) (finding irreparable injury is not necessary to
 9 obtain a preliminary injunction when statutory conditions satisfied) (internal citations omitted). Thus,
 10 the government is not required to prove the injury or the public interest factors when seeking an
 11 injunction under a statute authorizing injunctive relief.⁷ *United States v. Fed. Deposit Ins. Corp.*, 881
 12 F.2d 207, 210 (5th Cir. 1989) (internal citations omitted).

13 2. Defendants Have Repeatedly Violated the Act, 21 U.S.C. §§ 331(a) and (k)

14 Section 331 of Title 21 of the United States Code provides, in relevant part:

15 The following acts and the causing thereof are prohibited:

16 (a) The introduction or delivery for introduction into interstate
 17 commerce of any food . . . that is adulterated

18 * * *

19 (k) . . . [T]he doing of any [] act with respect to[] a food . . . while such article is held for sale .
 . . after shipment in interstate commerce and results in such article being adulterated

20 21 U.S.C. § 331(a), (k). The elements for establishing a violation of 21 U.S.C. § 331(a) are: (1) the
 21 product in question is a food; (2) the food is adulterated; and (3) the food has been introduced or
 22 delivered for introduction in interstate commerce. The elements for establishing a violation of 21 U.S.C.
 23 § 331(k) are: (1) the product in question is a food; (2) Defendants' acts cause the food to be adulterated;
 24 and (3) the food is held for sale after it has traveled in interstate commerce.

25 As set forth in Section IV(A)(1)(a), it is undisputed that the product in question – i.e., cheese – is

26
 27 ⁷ Although in *United States v. Nutri-Cology*, 982 F.2d 394, 398 (9th Cir. 1992), the Ninth Circuit
 28 held that in a statutory injunction case in which the government makes merely a “colorable evidentiary
 showing” of a violation of the Act, the government bears a greater burden of establishing the possibility
 of irreparable injury, *id.*, *Nutri-Cology* standard does not apply here, because the government’s evidence
 here reflects far more than merely a “colorable evidentiary showing.”

1 as a “food” under the Act. Thus, the first prongs of 21 U.S.C. § 331(a) & (k) are satisfied.

2 The evidence discussed in Section IV(A)(1)(c), *supra*, satisfies the second prongs of 21 U.S.C. §
3 331(a) & (k), in that it establishes that the food is adulterated under 21 U.S.C. § 342(a)(4), and that
4 Defendants’ actions caused the food to be adulterated by preparing, packing, and holding such food
5 under insanitary conditions whereby it may have become contaminated with filth, or whereby it may
6 have been rendered injurious to health.

7 The third prong of 21 U.S.C. § 331(a) is satisfied because Defendants have introduced adulterated
8 food into interstate commerce. FDA has documented sales and shipments of the Creamery’s adulterated
9 cheese from the Creamery in Washington to a customer in Portland, Oregon.⁸ Breen Decl. ¶ 7, Ex. B-1.
10 Defendant Kelli Estrella admits that the Creamery also sold cheese to customers in New York,
11 California, and Florida. Estrella Aff. ¶ 21. Thus, Defendants have violated 21 U.S.C. § 331(a) by
12 introducing into interstate commerce food that is adulterated.

13 The third prong of a 21 U.S.C. § 331(k) is also satisfied because Defendants have held their
14 adulterated food for sale after shipment of one or more of the food’s ingredients (e.g., the rennet) in
15 interstate commerce. *See* Section IV(A)(1)(b), *supra*. Thus, Defendants have violated 21 U.S.C.
16 § 331(k) by doing an act with respect to an article of food while such article is held for sale after
17 shipment in interstate commerce and results in such article being adulterated.

18 3. Defendants Are Likely to Continue to Violate the Act Unless Enjoined

19 Although Defendants have represented that they are not presently distributing cheese from the
20 Creamery, the injunctive relief sought in the Amended Complaint is appropriate and necessary to guard
21 against food safety concerns should the firm resume operations. Defendants’ history of serious
22 violations and defiant behavior, plus Defendants’ stated intent to resume cheese manufacturing,
23 establishes a strong likelihood that Defendants will continue to violate the Act. Injunctive relief is thus
24 warranted and appropriate. *See, e.g., Rhody Dairy*, 812 F. Supp. 2d at 1246 (“Defendants have
25 demonstrated a prolonged resistance to conformance with the regulations imposed by the FDA and have
26 not taken measures to achieve compliance, despite several notices provided by the Government

27
28 ⁸ The Oregon firm received one of those shipments on August 10, 2010, just one week after FDA
investigators collected environmental samples from the Creamery’s environment that subsequently
tested positive for *L. mono* contamination.

1 subsequent to the inspections . . . Furthermore, there is scant indication that Defendants' have taken
 2 measures to bring themselves into lasting compliance so as to cure themselves of the violations.”).

3 Indeed, Defendants’ past actions strongly suggest that they are unwilling or unable to come into
 4 compliance on their own. After recalling and destroying significant amounts of cheese because of
 5 positive *L. mono* test results, Defendants temporarily shut down their operations and “sought out
 6 professional assistance” in Spring of 2010. *See Estrella Aff.* ¶ 31. However, subsequent testing and
 7 PFGE analyses revealed that the same strain of *L. mono* likely persisted in Defendants’ facility and thus
 8 Defendants’ voluntary efforts were ineffective at eliminating *L. mono* from the Creamery.

9 Even after the government notified Defendants of the continued presence of *L. mono* in their
 10 facility, Defendants resisted the government’s guidance and authority. On at least one occasion in
 11 September 2010, when FDA asked Defendants to recall potentially contaminated cheese, Defendants
 12 refused, leaving adulterated and potentially hazardous cheese on the market to be purchased and
 13 consumed by unsuspecting consumers. *See Breen Decl.* ¶ 12. Additionally, Defendant Kelli Estrella
 14 admits that while the seized cheese was in the custody of this Court, and without the permission of this
 15 Court or the knowledge or supervision of FDA, the Defendants used the seized cheese as animal feed.
 16 *See Estrella Aff.* ¶ 45. Defendants have also defied FDA’s well-founded concerns regarding the use of
 17 wooden shelves because they “prefer to follow time honored wisdom rather than conventional industrial
 18 food practices.” *Id.* at ¶ 53.

19 In sum, in light of Defendants’ history of non-compliance with FDA’s food safety requirements
 20 and their defiance toward both FDA and this Court, the United States believes that injunctive relief is
 21 necessary to prevent future violations of the FDCA and to protect the public health.⁹

22 C. Voluntary Cessation of Illegal Activity Does Not Moot the Controversy

23 It is well established that voluntary cessation of illegal activity does not moot an action for
 24 injunctive relief “unless it can be said with assurance that there is no reasonable expectation that the
 25 alleged violation will recur, and (2) interim relief or events have completely and irrevocably eradicated

26
 27 ⁹ It should be noted that if Defendants – per their counsel’s representations – resume cheesemaking,
 28 but attempt to keep all of their activities and ingredients solely intrastate, including using ingredients
 originating intrastate, injunctive relief is nonetheless appropriate and necessary because the injunction
 would serve to protect the public in the event that Defendants (intentionally or unintentionally) engage in
 interstate activities regulated by the FDCA.

1 the effects of the alleged violation.” *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979) (citing
2 *W. T. Grant Co.*, 345 U.S. at 632) (internal quotations and citations omitted).

3 For the reasons discussed above, it is reasonable to expect that Defendants’ violative behavior *will*
4 recur when Defendants resume cheese-making operations. Accordingly, the government respectfully
5 submits that injunctive relief is necessary and appropriate.

6 V. CONCLUSION

7 FDA has brought this action under the Act, which “imposes not only a positive duty to seek out
8 and remedy violations when they occur but also, and primarily, a duty to implement measures that will
9 insure that violations will not occur.” *United States v. Park*, 421 U.S. 658, 672 (1975). Rather than
10 place the risk on the consuming public, the Supreme Court has held on numerous occasions that the
11 burden for placing safe food into interstate commerce properly falls on the manufacturer who profits and
12 has the ability to control its business. *Id.*; *see also United States v. Dotterweich*, 320 U.S. 277, 285
13 (1943) (“Balancing relative hardships, Congress has preferred to place it upon those who have at least
14 the opportunity of informing themselves of the existence of conditions imposed for the protection of
15 consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who

16 //

17 //

1 are wholly helpless.”). For the foregoing reasons, the government respectfully requests that this Court
2 grant summary judgment in favor of the government and enter an order of condemnation and permanent
3 injunction. A proposed order of condemnation and permanent injunction is submitted herewith.

4
5 Dated this 16th day of August, 2012.

6 Respectfully submitted,

7 :
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that she is an employee in the Office of the United States Attorney for the Western District of Washington and is a person of such age and discretion as to be competent to serve papers;

That on August 16, 2012, she electronically filed the aforementioned document(s) with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the attorney(s) of record as follows:

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s / Patricia Buyce

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