IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
v.	)	Criminal Action No. 16- 13 - SRF
	)	
ROOS FOODS, INC.,	)	
	)	
Defendant.	)	

INFORMATION

The United States Attorney for the District of Delaware charges that:

COUNT ONE

At all times material to this information:

1. Defendant ROOS FOODS, INC. ("ROOS FOODS"), located in Kenton, Delaware, manufactured various ready-to-eat cheeses, including ricotta, queso fresco, and fresh cheese curd, and sold and distributed its products to wholesale customers in Maryland, Virginia, Washington D.C., and New Jersey.

2. The United States Food and Drug Administration ("FDA") is the federal agency responsible for protecting the health and safety of the American public by enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq. One purpose of the FDCA is to ensure that human and animal food distributed in the United States is safe and fit for consumption.

3. The term "food" is defined in the FDCA as articles "used for food or drink for man or other animals" as well as articles used as components of any food. 21 U.S.C. § 321(f)(1) and (3).

4. Under the FDCA, it is a prohibited act to introduce or deliver for introduction into interstate commerce any food that is adulterated. 21 U.S.C. § 331(a).

5. A food is deemed adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. 21 U.S.C. § 341(a)(4).

6. In determining whether a food was prepared, packed, or held under insanitary conditions that may have rendered it injurious to health, the criteria and definitions in FDA's regulations regarding Current Good Manufacturing Practice apply. 21 C.F.R. § 110.5. Current Good Manufacturing Practice includes having processes and controls in place to ensure that all operations in the receiving, transporting, segregating, preparing, manufacturing, packaging, and storing of food are conducted in accordance with adequate sanitation principles, and that appropriate quality control operations are employed to ensure that food is suitable for human consumption. 21 C.F.R. § 110.80.

7. Current Good Manufacturing Practice includes the following requirements: (1) the manufacturing plant and grounds are constructed in such a manner as to prevent drip from contaminating food-contact surfaces and food packaging materials, 21 C.F.R. § 110.20(b)(4); (2) food-contact surfaces are cleaned as frequently as necessary to protect against contamination of food, 21 C.F.R. § 110.35(d); (3) raw materials and other ingredients are stored in a manner that protects against contamination, 21 C.F.R. § 110.80(a)(1); (4) the manufacturing plant and

grounds are constructed in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept in good repair, 21 C.F.R. § 110.20(b)(4); and (5) the equipment and utensils are used in a manner that precludes the adulteration of food with contaminated water and other contaminants, 21 C.F.R. § 110.40(a).

Listeria Monocytogenes

8. *Listeria Monocytogenes* ("*L. mono*") is the bacterium that causes the disease listeriosis. Listeriosis is most commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for high-risk groups such as unborn babies, newborns, and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia, often leading to death. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or septicemia in the newborn.

9. Unlike many other foodborne microbes, *L. mono* bacteria are capable of adapting and growing even at refrigerator temperatures. *L. mono* is also capable of surviving and growing under other adverse conditions, such as high salt or high acid (low pH) conditions. Thus, the presence of *L. mono* in ready-to-eat foods is a particularly significant public health risk.

Listeriosis Outbreak

10. On February 15, 2014, the Virginia Department of Agriculture and Consumer Service ("VDACS") reported that *L. mono* had been isolated from cheese manufactured by ROOS FOODS and collected by VDACS at a retail store in Virginia.

11. On February 19, 2014, the Maryland Department of Health and Mental Hygiene ("MDHMH") reported presumptively positive results for *Listeria* in tests of cheese products manufactured by ROOS FOODS. This result was later confirmed.

12. On February 21, 2014, the Centers for Disease Control and Prevention ("CDC") reported that a total of eight people (5 adults and 3 newborns) in two states (Maryland and California) were infected with *L. mono*, with isolation dates ranging from August 1 – November 27, 2013. CDC stated that several of the patients in Maryland reported eating soft or semi-soft cheese in the month before becoming ill.

13. FDA and VDACS performed Whole Genome Sequencing in the *L. mono* strains isolated from the ROOS FOODS cheese products and found them to be highly related to those *Listeria* strains isolated from patients in the Maryland *L. mono* outbreak. The tests showed that the clinical isolates of *L. mono* originated from a single bacteria lineage and that it was reasonably likely that the lineage shared the same geographic locale.

The FDA Inspection

14. Following VDAC's report that *L. mono* had been isolated from cheese manufactured by ROOS FOODS, FDA inspected defendant's Kenton, Delaware facility from February 18 to March 4, 2014. This inspection established that ready-to-eat cheese products that defendant manufactured, processed, packed, labeled, held, and distributed were adulterated within the meaning of 21 U.SC. § 342(a)(4) in that they had been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health. At the close of the March 2014 Inspection, FDA investigators issued a ten-item List of Inspectional Observations ("Form FDA-483") that contained the following

observations of failures to implement effective monitoring and sanitation controls in accordance with the Current Good Manufacturing Practice requirements for food, see 21 C.F.R. Part 110, among others:

A. Failure to construct the facility in such a manner as to prevent drip from contaminating food-contact surfaces and food packaging materials, as required by 21 C.F.R. § 110.20(b)(4);

B. Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food, as required by 21 C.F.R. § 110.35(d);

C. Failure to store raw materials and ingredients in a manner that protects against contamination, as required by 21 C.F.R. § 110.80(a)(1);

D. Failure to construct the facility in such a manner as to allow floors, walls, and ceilings to be adequately cleaned and kept clean and in good repair, as required by 21 C.F.R. § 110.20(b)(4); and

E. Failure to use equipment and utensils in a manner that precludes the adulteration of food with contaminated water and contaminants, as required by 21 C.F.R. § 110.40(a).

15. The FDA inspection revealed significant sanitation deficiencies, such as widespread roof leaks in the manufacturing area, including over open manufacturing equipment; rust flakes on the manufacturing equipment from corroded roof trusses and metal roofing; un-cleanable surfaces on walls, floors, and ceilings; and product residue on equipment that had purportedly been cleaned.

16. FDA investigators collected environmental samples during the inspection and found *L. mono* on twelve surfaces in the facility, including a cutting board, the bottom of the cheese press, scrub brush bristles, the floor drain in the refrigerated storage room, a utility table in the packaging room, and the broken welds on a mobile storage tank.

17. On March 11, 2014, FDA suspended the food facility registration of ROOS FOODS after determining there was a reasonable probability that food manufactured, processed, packed, or held by ROOS FOODS would cause serious adverse health consequences or death to humans. A company without a food facility registration cannot distribute any food products.

Previous Inspections

18. FDA previously inspected Defendant's facility between June 3–4, 2013 (the "June 2013 Inspection"). Some of the CGMP deviations observed during the February 2014 Inspection, discussed in paragraph 15, were the same as, or similar to, those FDA observed during the June 2013 Inspection. For example, during the June 2013 Inspection, FDA documented Defendant's failure to: (a) clean food-contact surfaces as frequently as necessary to protect against contamination of food (similar to paragraph 15(B) above); (b) handle work-in progress in a manner that protects against contamination (similar to paragraph 15(C) above); and (c) maintain buildings, fixtures, or other physical facilities in a sanitary condition (similar to paragraph 15(D) above). Investigators observed, among other things, condensation accumulated on areas above food contact surfaces and equipment, corroded and rusted equipment that was difficult to clean, and gaps in the ceiling in the refrigerated storage room. At the close of the June 2013 Inspection, FDA investigators issued a Report of Investigational Observations to ROOS FOODS management and discussed each of the observations with them.

19. FDA also previously inspected Defendant's facility between July 13–20, 2010 (the "July 2010 Inspection"). Some of the CGMP deviations observed during the February 2014 Inspection, discussed in paragraph 15, were the same as, or similar to, those observed by FDA during the July 2010 Inspection. For example, during the July 2010 Inspection, FDA documented Defendant's failure to: (a) construct the plant in such a manner as to prevent drip and condensate from contaminating food and food-contact surfaces (similar to paragraph 12(A) above); (b) construct the plant in such a manner as to allow ceilings to be adequately cleaned and kept clean (similar to paragraph 12(D) above); and (c) 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 (similar to paragraph 12(E) above). Investigators observed, among other things, standing water on production floors; condensate accumulations on areas above food contact surfaces; deteriorated surfaces on food processing equipment; and difficult to clean ceilings in the cheese curd production room. At the close of the July 2010 Inspection, FDA investigators issued a ten-item Report of Investigational Observations to ROOS FOODS management and discussed each of the observations with them.

CHARGING PARAGRAPH

20. Paragraphs 1 – 19 above are hereby incorporated by reference.

21. From in or about February 15, 2014, through in or about March 2014, in the District of Delaware and elsewhere, defendant

ROOS FOODS, INC.

introduced and delivered for introduction into interstate commerce adulterated food, that is, cheese, that was manufactured, processed, packed, and held under insanitary conditions whereby

it may have become contaminated with filth or rendered injurious to health within the meaning of Title 21, U.S.C. Section 342(a)(4).

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(1).

NOTICE OF FORFEITURE

The United States Attorney for the District of Delaware charges that:

22. As a result of the violation of Title 21, United States Code, Sections 331(a) and 333(a)(1) set forth in this Information, defendant

ROOS FOODS, INC.

shall forfeit to the United States any quantities of certain foods which were deemed adulterated as a matter of federal law in the United States when delivered for introduction into interstate commerce.

23. If any of the property subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property subject to forfeiture.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

CHARLES M. OBERLY, III
United States Attorney

By: _____
Edmond Falgowski
Assistant United States Attorney

Dated: 1/22/16

for _____
Heide L. Herrmann
Trial Attorney
Consumer Protection Branch
United States Department of Justice