

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA : **CRIMINAL NO. 12- _____**
v. : **DATE FILED: _____**
LEBANON CHEESE COMPANY, INC. : **VIOLATIONS:**
JOSEPH G. LOTITO : **21 U.S.C. §§ 331(a), 342(a)(3), 333(a)(1)**
: **(Introducing adulterated food into**
: **interstate commerce - 1 count)**

INFORMATION

COUNT ONE

Introduction

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this information:

1. Defendant **LEBANON CHEESE COMPANY, INC.** (“**LEBANON CHEESE COMPANY**”), located in Lebanon, New Jersey, manufactured various types of cheese, including Ricotta cheese, and sold and distributed its products to restaurants, delis, bakeries and ravioli manufacturers, among others.
2. Defendant **JOSEPH G. LOTITO** was the president and owner of defendant **LEBANON CHEESE COMPANY**.
3. Ricotta Impastata cheese, a product manufactured by defendant **LEBANON CHEESE COMPANY, INC.**, was a specially prepared ricotta cheese often considered to be one of the highest quality ricotta cheeses available on the market. One of the essential ingredients used in the manufacture of this product was milk.

4. The United States Food and Drug Administration ("FDA") was 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 was to ensure that human and animal food distributed in the United States was safe and fit for consumption.

5. The term "food" was 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),(3).

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

7. The FDCA defined myriad ways a food was deemed adulterated. Under 21 U.S.C. § 342(a)(2)(C)(ii), a food was deemed adulterated if it bore a new animal drug (or conversion product of such drug) that was unsafe within the meaning of 21 U.S.C. § 360b. A new animal drug was unsafe within the meaning of 21 U.S.C. § 360b unless, among other things, FDA had approved the drug for the intended use and the drug, its labeling, and such use conformed to FDA's approved new animal drug application. 21 U.S.C. § 360b(a)(1)(A). FDA's approval of a drug's intended use and labeling often required that the edible products of food-producing animals contained no more than a stated level – or tolerance – of the drug. These tolerances, in addition to being stated in the labeling of the drug, were listed in the Code of Federal Regulations ("CFR"). See 21 C.F.R. § 556.1(a). If an edible product of a food producing animal, such as milk, for example, contained the drug in an amount over the allowable tolerance, it was deemed unsafe under the FDCA and adulterated. 21 U.S.C. § 342(a)(2)(C)(ii).

8. A food was also deemed adulterated if it consisted in whole or part of any filthy, putrid, or decomposed substance, or if it was otherwise unfit for food. 21 U.S.C. § 342(a)(3). In determining whether an article was "unfit for food," the criteria and definitions in FDA's regulations regarding Current Good Manufacturing Practice applied. 21 C.F.R. § 110.5. Current Good Manufacturing Practice included having processes and controls in place to ensure that all operations in the receiving, transporting, segregating, preparing, manufacturing, packaging, and storing of food were conducted in accordance with adequate sanitation principles, and that appropriate quality control operations were employed to ensure that food was suitable for human consumption. 21 C.F.R. § 110.80. This included the requirement that raw materials and other ingredients be inspected and segregated and otherwise handled as necessary to ascertain that they were suitable for processing into food. 21 C.F.R. § 110.80(a)(1). Food, raw materials, and other ingredients that were adulterated within the meaning of the FDCA were required to be disposed of in a manner that protected against the contamination of other food. 21 C.F.R. § 110.80(b)(9).

The Regulation of Milk in Pennsylvania

9. The FDA required that all milk and milk fluid products be screened for six beta lactum drug residues: Ampicillin, Amoxicillin, Cephapirin, Ceftiofur, Cloxacillin, and Penicillin. These beta lactum antibiotics were frequently used by dairy farmers to treat disease in lactating dairy cows and were the most likely to cause a residue in milk. Beta lactum drug screening of milk was performed for two main reasons: first, to reduce the likelihood of a person suffering an allergic or anaphylactic reaction to the beta lactum antibiotics; and second, to mitigate increased tolerance to antibiotic drugs in humans. By regulation, FDA established

tolerances for each of these beta lactum drugs for negligible residues in milk and in the uncooked edible tissues of cattle. Any residue above these tolerances deemed the food unsafe under 21 U.S.C. § 346, and adulterated under 21 U.S.C. § 342(a)(1). The tolerances for the six beta lactum drugs in milk ranged from 0 (penicillin), where any amount rendered the food unsafe, to 0.1 parts per million (ceftiofur). See 21 C.F.R. § 556.113, 556.510.

10. There were fifteen FDA-approved screening tests accepted and used by the dairy industry to screen for the presence of beta lactum antibiotics. One of the more common screening tests used by the milk industry in Pennsylvania was manufactured by Charm Sciences, Inc., and frequently was referred to as the "Charm Milk Test." This test analyzed a small amount of milk for the presence of beta lactum antibiotics and provided a positive or negative reading in only a few minutes. The test did not identify which specific beta lactum antibiotic was present in the milk or the exact amount in parts per million. These screening tests were configured to provide a positive reading for beta lactum antibiotics just below or near the acceptable tolerance level set out in FDA regulations. The tests were an industry-accepted method of quickly screening the perishable milk product and were less expensive and time consuming than the tests that would affirmatively identify the exact drug and the exact level in a sample.

11. In Pennsylvania, raw milk was transported from dairy farms to large dairy processors, usually by independently owned trucking companies, of which D.A. Landis Trucking Company (charged separately) was one. The milk hauled by trucking companies was owned by the large dairy processors who purchased the milk from the individual dairy farmers. The Pennsylvania Milk Marketing Board (PA MMB), located in Harrisburg, Pennsylvania, issued Weigher/Sampler permits to trucking companies and drivers who hauled milk. Sampling milk

allowed for loads testing positive for beta lactum antibiotics to be traced back to the producer farm by the Pennsylvania Department of Agriculture or FDA. When the milk pick-up route was completed, the trucking company transported the commingled milk from all the farms to the dairy processing plant. Upon arrival at the dairy processing plant and prior to it being unloaded from the truck, the commingled milk was screened for beta lactum antibiotics. If the milk load tested positive for beta lactum antibiotics in two successive tests using one of the FDA and industry-approved screening methods, such as the "Charm Milk Test," the milk was condemned and the dairy processor would reject the load and instruct the hauler to dispose of it. The Pennsylvania Drug Residue Testing Program required the dairy processor to report the disposal location of the milk and additional facts to the Pennsylvania Department of Agriculture.

Defendants' Use of Condemned Milk to Manufacture Cheese

12. From in or about January, 2008 or earlier to in or about July, 2009, D.A. Landis Trucking, Inc. (charged separately) hauled milk from approximately 700 individual dairy farms in Southeastern Pennsylvania to large dairy processors. At least 20 of these loads tested positive for beta lactum antibiotics using FDA-approved screening tests and were condemned and ordered to be destroyed by the dairy processor.

13. The dairy processors, based on information from D.A. Landis Trucking, Inc., reported to the Commonwealth of Pennsylvania that the condemned milk was dumped at a local farmer's manure pit in Willow Street, Pennsylvania. In truth, however, the drivers of the rejected loads were told by Dean Landis, the owner of the company (also charged separately) to return the condemned loads to the trucking yard, where they were pumped into another truck.

14. D.A. Landis Trucking, Inc. drivers then delivered the condemned loads of milk to defendant JOSEPH LOTITO at defendant LEBANON CHEESE COMPANY in Lebanon, New Jersey. Defendant JOSEPH LOTITO purchased the condemned milk for approximately \$4 per hundred pounds, where the going rate for raw milk at that time ranged from approximately \$12 to \$23 per hundred pounds, depending on the intended end use. The drivers and the owner of the trucking company were paid in cash.

15. Defendants JOSEPH LOTITO and LEBANON CHEESE COMPANY did not further test or analyze the condemned milk to determine if it was fit for food and instead used the milk in the manufacture of Ricotta cheese, which was then distributed to customers.

16. On or about August 20, 2008, in the Eastern District of Pennsylvania and elsewhere, defendants

**LEBANON CHEESE COMPANY, INC. and
JOSEPH G. LOTITO**

introduced and delivered for introduction into interstate commerce adulterated food, that is, eight 10-pound containers of Ricotta Impastata cheese delivered to a food market in Wyomissing, Pennsylvania, that was unfit for human consumption because it was manufactured from truckloads of raw milk that had been condemned by Pennsylvania dairy processors for failing screening tests for the presence of beta lactum antibiotics.

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


ZANE DAVID MEMEGER
United States Attorney