UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, Plaintiff, vs. DIANE LOUISE ZOLLINGER, an individual, doing business as FELIX CUSTOM SMOKING, a sole proprietorship. Defendant.	Case No.: 22-cv-00278 **COMPLAINT**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration (FDA), respectfully represents to this Court as follows:

1. This action is brought by the United States of America under the Federal Food, Drug, and Cosmetic Act (the Food & Drug Act), 21 U.S.C. § 332(a), to enjoin and restrain Diane Louise Zollinger, doing business as Felix Custom Smoking, a sole proprietorship from violating 21 U.S.C. § 331(k), by causing food to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (4) while such food is held for sale after shipment of one or more of its components in interstate commerce.

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JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

PARTIES

4. Plaintiff is the United States of America.

5. Defendant Diane Louise Zollinger, an individual, operates as through Felix Custom Smoking, a sole proprietorship in Washington State, with a facility at 17461 147th Street Southeast Suite 2A, Monroe, Washington, within the jurisdiction of this Court.

7. Defendant manufactures ready-to-eat seafood products, including jerky, hot smoked and cold smoked salmon. Orders are typically picked up on-site by customers and the facility does not offer its products for sale online.

8. Defendant primarily processes seafood products for private companies that pick up the seafood and independently distribute the seafood products.

9. Defendant also processes seafood products for retail consumers, as well as selling branded products to the public at a retail store on-site at her facility. Through Felix Custom Smoking, she also sells the jerky, hot smoked and cold smoked salmon wholesale to a farmers' market vendor.

10. Defendant has shipped products to out-of-state customers in Idaho and Colorado. She also processes fish from Alaska, and receives the salt and sugar used in the processing of her seafood products from out-of-state suppliers through interstate commerce.

HAZARDS PRESENTED BY DEFENDANT'S FOOD

Listeria monocytogenes

11. *Listeria monocytogenes* (*Listeria mono*) is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *Listeria*. Listeriosis can be serious, even fatal, especially for vulnerable groups such as newborns and immunocompromised

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people. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or septicemia in the newborn. *Listeria mono* is the major pathogen, and one of several bacterium, contained within the *Listeria* species.

12. *Listeria mono* can survive and grow under adverse conditions, such as refrigeration temperatures and high salt or high-acid conditions (low pH). *Listeria mono* can colonize on moist surfaces such as floors, floor drains, wet areas, and processing equipment.

13. To minimize the potential for *Listeria mono* contamination, it is necessary to have sanitation procedures that prevent contamination of food contact surfaces and to eliminate niches where *Listeria mono* can become established, grow, and persist. Strict in-plant sanitation measures must be taken to eliminate *Listeria mono* and prevent its proliferation.

14. The presence of *Listeria mono* in a facility processing ready-to-eat foods presents a particularly significant public health risk.

Clostridium Botulinum

15. *Clostridium botulinum* (*C. botulinum*) is an anaerobic bacterium, which allows it to thrive in oxygen-free environments. All people are susceptible to *C. botulinum*'s neurotoxin that *C. botulinum* spores can produce in food. Ingesting even a small amount of this neurotoxin can cause botulism. Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate, if not treated promptly.

16. *C. botulinum* is a pathogen that is widely distributed in nature and may be found in any raw fish or fishery product. Because its spores are heat-resistant, *C. botulinum* can survive cooking. *C. botulinum* can also survive in food that has been incorrectly or minimally processed. Certain strains of *C. botulinum*, called proteolytic strains, produce offensive odors and tastes in food products, and can grow at temperatures as low as 50°F. In contrast, although non-proteolytic strains of *C. botulinum* do not produce the offensive odors or tastes, the non-proteolytic strains are much more dangerous because they can grow and produce toxin at

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refrigeration temperatures as low as 38°F, thus rendering a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. botulinum* can occur at temperatures above 38°F. To inhibit the growth of non-proteolytic *C. botulinum* in smoked seafood products, processors must employ adequate levels of salt or salt-nitrite combinations in brining solutions in conjunction with proper smoking and drying. Processors must also store smoked products in adequate refrigeration temperatures to inhibit the growth of proteolytic *C. botulinum*.

17. The Food & Drug Act and its implementing regulations require a seafood processor to control the risk of *C. botulinum* and *Listeria mono* formation if the bacteria are reasonably likely to grow in the processor's seafood products. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(a)-(c).

LEGAL FRAMEWORK

18. Defendant's ready-to-eat fish and fishery products are "food" within the meaning of the Food & Drug Act. *See* 21 U.S.C. § 321(f).

19. Food is adulterated if it bears or contains a poisonous or deleterious substance, such as *Listeria mono*, which may render the food injurious to human health. 21 U.S.C. § 342(a)(1).

20. Food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) "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. A seafood processor's failure to comply with the requirements of the seafood Hazard Analysis and Critical Control Point (HACCP) regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Food & Drug Act. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 123.6(g), 123.12(d).

22. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of each kind of fish or

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fishery product that it processes. 21 C.F.R. § 123.6(a). A food safety hazard is "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." 21 C.F.R. § 123.3(f).

23. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing, the processor must develop and implement an adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

A. Identify critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce a food safety hazard to an acceptable level. *See* 21 C.F.R. §§ 123.3(b) and 123.6(c)(2); and

B. Identify critical limits at each CCP, which are the maximum or minimum values within which a physical, biological, or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). *See* 21 C.F.R. §§ 123.3(c) and 123.6(c)(3).

24. A seafood processor must also:

A. Take corrective action whenever a deviation from a critical limit occurs. 21 C.F.R. § 123.7;

B. Verify that its HACCP plan is adequate to control food safety hazards reasonably likely to occur and that the plan is being effectively implemented. 21 C.F.R. § 123.8(a);

C. Record its sanitation activities, 21 C.F.R. § 123.11(c), and maintain additional appropriate records, such as documentation of CCPs, corrective actions taken, and HACCP plan verification activities. 21 C.F.R. §§ 123.6-123.9; and

D. Monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the Current Good Manufacturing Practice ("cGMP") requirements for food, including prevention of cross-contamination from insanitary objects and exclusion of pests. 21 C.F.R. § 123.11(b) and 21 C.F.R. Part 117.

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25. Defendant is subject to the seafood HACCP regulations because she engages in the "processing," as defined at 21 C.F.R. § 123.3(k)(1)(iii), of "fish" or "fishery product," as defined at 21 C.F.R. §§ 123.3(d) and (e).

26. Food is adulterated under 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with the cGMP regulations for food. 21 C.F.R. Part 117; 21 C.F.R. § 117.1(a).

DEFENDANT'S VIOLATIONS

27. Defendant violates 21 U.S.C. § 331(k) by causing articles of food to become adulterated within the meaning of 21 U.S.C. §§ 342(a)(1) and (4) while such articles are held for sale after shipment of one or more components in interstate commerce.

28. Defendant's food is adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that she fails to comply with the seafood HACCP regulations, 21 C.F.R. Part 123, by, among other deficiencies, failing to adequately control for the risk of *Listeria mono* and *C. botulinum* toxin formation in her fish or fishery products, and by preparing, packing, or holding the fish or fishery products under insanitary conditions whereby it may have been contaminated with filth or may have been rendered injurious to health.

HISTORY OF INSPECTIONS

29. Defendant has had multiple instances of positive *Listeria mono* findings in environmental samples taken by FDA from various locations throughout Defendant's facility as well as in Defendant's finished seafood product. Also, Defendant has an extensive history of processing seafood products under grossly insanitary conditions. This pattern of continuing violative conduct has been documented by FDA inspectors during inspections on July 19 to September 8, 2021 and August 21 to September 19, 2018.

30. FDA inspectors collected 104 environmental subsamples from food contact and non-food contact surfaces during the 2021 inspection.

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31. Subsequent testing by FDA revealed the presence of *Listeria mono* in 19 of the 104 samples collected from food processing areas of the facility. Of the 19 positive subsamples, five were from food contact surfaces and two were from ready-to-eat surfaces, which are surfaces where Defendant processes ready-to-eat seafood product.

32. To determine whether insanitary conditions at Defendant's facility allowed the harborage of a resident strain of *Listeria mono*, FDA conducted whole genome sequencing (WGS) analysis on the *Listeria mono* isolates from the environmental samples collected by FDA during the 2021 and 2018 inspections. WGS is used to determine whether different samples of bacteria are the match. WGS analysis of the samples taken from the 2021 and 2018 inspection showed that the bacteria matched, and a resident strain of *Listeria mono* has been established in Defendant's facility.

33. On August 19, 2021, Loki Fish Company (Loki), a wholesale customer, located in Seattle, Washington, tested a sample of cold smoked salmon lox that Loki had purchased from Defendant.

34. On August 23, 2021, the testing confirmed the presence of *Listeria mono* in the cold smoked salmon lox sample Loki had submitted. Loki conducted a voluntary recall. FDA tested Loki's sample of cold smoked salmon lox for *Listeria mono* and using WGS analysis found strong evidence that the strain of *Listeria mono* in the cold smoked salmon lox matched the resident strain of *Listeria mono* in Defendant's facility.

35. The presence of such a strain is evidence of a seafood processor who has failed to maintain a clean facility and has created an ideal environment for dangerous pathogens to contaminate her seafood products.

MOST RECENT INSPECTION

36. FDA most recently inspected Defendant's facility in the 2021 inspection. At the close of this inspection, FDA inspectors issued Defendant a List of Inspectional Observations (Form FDA-483) that included the following observations:

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A. Defendant fails to monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with cGMP, including the condition and cleanliness of food contact surfaces and prevention of cross-contamination from insanitary objects in violation of 21 C.F.R. § 123.11(b)(2) and 21 C.F.R. § 117.35(d). For example, FDA inspectors observed that the slicer for ready-to-eat products was soiled in several places and had tape and rubber bands holding pieces of the slicer together, thus, making cleaning even harder. Inspectors also observed an employee disassembling parts of the ready-to-eat slicer and washing those parts in the handwashing sink, which can transfer pathogens and filth from the handwashing sink to the ready-to-eat slicer parts to potentially contaminate ready-to-eat food;

B. Defendant fails to maintain her plant in a clean manner and in good repair to prevent seafood from becoming adulterated, in violation of 21 C.F.R. § 123.11(b)(3); 21 C.F.R. § 117.80(c)(2), and 21 C.F.R. § 117.35(a). For example, FDA inspectors observed heavily soiled drains in both the processing and slicing areas of the facility. FDA inspectors also observed standing water in areas where employees frequently transported wheeled equipment containing ready-to-eat fishery products. Improperly cleaned drains and pooled standing water can provide suitable environments for the growth of pathogens that can cross contaminate ready-to-eat food. In addition, the inspectors noted that the floor was cracked and chipped, which can make cleaning more difficult and provide a place for bacteria to grow;

C. Defendant fails to monitor conditions and practices with sufficient frequency to ensure food, food packaging material, and food contact surfaces are protected from the adulterant of condensate, in violation of 21 C.F.R. § 123.11(b)(5) and 21 C.F.R. § 117.20(b)(4). For example, inspectors observed condensate dripping from a condenser in the ready-to-eat slicing and packaging room walk-in cooler. Condensate is a known source for *Listeria mono*;

D. Defendant fails to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of the product by pests, in violation of 21 C.F.R. § 123.11(b)(8) and 21 C.F.R. § 117.35(c). For

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example, FDA inspectors observed both dead and live flies at an amount too numerous to count. Investigators also observed flies landing on food contact surfaces;

E. Defendant fails to ensure that her HACCP plans list a critical limit that ensures control of one or more hazards, in violation of 21 C.F.R. § 123.6(c)(3). Specifically, FDA inspectors observed that the "Salmon Lox," "Kippered Nonscombrotoxin Fish," and "Salmon Jerky" HACCP plans all included critical limits that did not ensure control over one or more food safety hazards, including *Listeria mono* and *C. botulinum*;

F. Defendant fails to list adequate monitoring procedures in her HACCP plan, in violation of 21 C.F.R. § 123.6(4). For example, the HACCP plan for ready-to-eat cold smoked seafood products lists a monitoring procedure of visually checking the cooler temperature once a day, but that is inadequate to control for pathogen growth and toxin formation. It is critical to continuously monitor the cooler temperature to prevent growth and toxin formation by pathogens, including *C. botulinum* in ready-to-eat cold smoked seafood products;

G. Defendant fails to take corrective action to ensure no product enters commerce that is either injurious to health or is otherwise adulterated and fails to correct the cause of the deviation, in violation of 21 C.F.R. § 123.7. For example, FDA inspectors observed that all three of Defendant's HACCP plans for her ready-to-eat products listed inadequate corrective actions at every CCP;

H. Defendant fails to take corrective action when a deviation from a critical limit occurs, in violation of 21 C.F.R. § 123.7(a). Specifically, FDA inspectors collected several records showing that salmon jerky products were cooked below the stated critical limit that required the product to be cooked to a minimum of 175°F. Defendant did not take or document any corrective action;

I. Defendant fails to properly review monitoring records to ensure values are within critical limits, in violation of 21 C.F.R. § 123.8(a)(3)(i). For example, inspectors observed that Defendant had dated and initialed CCP monitoring records as having been reviewed, even

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though the records showed deviations from critical limits but no documentation showing any corrections to the deviations; and

J. Defendant fails to implement the verification procedures listed in her facility's HACCP plan, in violation of 21 C.F.R. § 123.8. For example, FDA inspectors observed that the firm manufactured and released multiple batches of ready-to-eat, hot and cold smoked and dried seafood products without verifying water phase salt ("WPS") levels or water activity levels according to the facility's corresponding HACCP plans.

37. Defendant's deficient cleaning and sanitation practices have led to the contamination of surfaces near food preparation areas with *Listeria mono*. Strict in-plant measures are necessary to control *Listeria mono*'s proliferation in Defendant's facility and to protect the public health.

2018 INSPECTION

38. The FDA inspected Defendant's facility from August 21 to September 19, 2018. At the end of the inspection, the FDA inspectors issued Defendant a Form FDA-483 that identified the following observations:

A. Defendant fails to take corrective action to ensure the affected product that does not meet the critical limits listed in the HACCP plan does not enter into commerce and that Defendant fails to identify and correct the reason for the deviation, in violation of 21 C.F.R. § 123.7. Specifically, FDA inspectors observed that the Micro-Chem WPS lab report dated August 30, 2017 identified a cold smoked salmon product as being below the required WPS level of 3.5. Defendant did not have any documentation of a corrective action that showed how this deviation was handled.

B. Defendant fails to implement the verification procedures listed in her HACCP plans, in violation of 21 C.F.R. § 123.6(b). Specifically, FDA inspectors observed that

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Defendant does not follow her verification procedure of conducting quarterly tests of the WPS level as required by her HACCP plan for two fishery products.

C. Defendant fails to manufacture and store food under the conditions and controls necessary to minimize the potential for microorganism growth and contamination, in violation of 21 C.F.R. § 117.80(b)(2). For example, inspectors collected an environmental sample from the center section of Defendant's smoking rack that tested positive for *Listeria mono*.

D. Defendant fails to monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with cGMP, including the condition and cleanliness of food contact surfaces and prevention of cross-contamination from insanitary objects in violation of 21 C.F.R. § 123.11. For example, FDA inspectors observed that the stainless-steel smokers and the adjacent floor area were unclean. Further, inspectors observed that her plant floor inside the smoking room was uneven, pitted, and could not be easily cleaned.

E. Defendant fails to take effective measures to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of the product by pests, in violation of 21 C.F.R. § 117.35(c). For example, FDA inspectors observed several flies inside the smoking room and inside the finished product packing room.

PRIOR NOTICE

42. Defendant has not provided a written response to the Form FDA-483 that FDA inspectors issued on September 8, 2021 to Defendant.

43. Defendant also did not provide a written response to the Form FDA-483 that FDA inspectors issued on September 19, 2018 to Defendant.

44. FDA held five calls with Defendant on August 9, 2021, August 17, 2021, August 25, 2021, August 27, 2021, and October 1, 2021 to discuss the significance of the pathogen findings in the environmental samples taken during FDA's August 2021 inspection and in the finished product sample obtained from Defendant's customer. FDA also discussed with

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Defendant the WGS analysis and the significance of finding a resident strain of *Listeria mono* in her facility.

45. FDA urged Defendant to take appropriate corrective actions during these calls. Defendant repeatedly declined to initiate a voluntary recall of her seafood products.

46. On August 13, 2021, FDA contacted Defendant's wholesale customers via telephone to notify them that the finished products processed by Defendant may be contaminated with *Listeria mono* and her customers should initiate their own voluntary recall.

47. On August 27, 2021, the FDA issued a public health advisory to alert consumers to the potential *Listeria mono* contamination in products processed by Defendant.

48. Defendant has not ceased operations and continues to process ready-to-eat seafood.

49. Defendant's deviations from the seafood HACCP regulations remain systemic and persistent. As a result, Defendant continues to fail to bring her operations into compliance with the law, and unless restrained by order of this Court, Defendant is likely to continue to violate 21 U.S.C. § 331(k).

WHEREFORE, the United States respectfully requests this Court to:

I. Order that Defendant cease receiving, preparing, processing, packing, labeling, holding, and/or distributing food unless and until Defendant bring her operations into compliance with the Food & Drug Act and applicable regulations, to FDA's satisfaction;

II. Preliminarily and permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendant, and any and all persons in active concert or participation with her, from directly or indirectly violating 21 U.S.C. § 331(k) by adulterating, or causing adulteration, within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342 (a)(4), of any food while such food is held for sale after shipment of one or more of its components in interstate commerce;

IV. Order that FDA be authorized to inspect Defendant's place(s) of business and all records relating to the receiving, preparing, processing, packing, labeling, holding, and/or

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distribution of food to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendant at the rates prevailing at the time the inspections are accomplished; and

V. Award the Plaintiff its costs incurred in pursuing this action, including the costs of inspection to date, and such other relief as the Court deems just and proper.

Dated this 9th day of March, 2022.

Respectfully submitted,

BRIAN M. BOYTON
Principal Deputy Assistant Attorney General,
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General
GUSTAV W. EYLER
Director
Consumer Protection Branch
ALLAN GORDUS
Assistant Director

By: /s/_____
SARAH WILLIAMS
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice, Civil Division
450 Fifth Street, N.W. 6th Floor, South
Washington, DC 20001
(202) 616-4269
sarah.williams@usdoj.gov

NICHOLAS W. BROWN
United States Attorney

By: /s/_____
KERRY KEEFE
Assistant United States Attorney
700 Stewart Street, Suite 5220
Seattle, WA 98101-1271
(206) 553-2640
kerry.keefe@usdoj.gov

Of Counsel:

DANIEL J. BARRY
Acting General Counsel
U.S. Dept. of Health & Human Services

MARK RAZA
Acting Chief Counsel
Food and Drug Administration

PERHAM GORJI
Deputy Chief Counsel, Litigation

LAUREN FASH
Assistant Chief Counsel for Enforcement
U.S. Dept. of Health & Human Services
Office of the General Counsel
Food and Drug Division
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Tel: (240) 731-8709
lauren.fash@fda.hhs.gov

Consumer Protection Branch
U.S. Department of Justice
450 5th St NW, Washington D.C. 20530
Main Line: (202) 307-0066