

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

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	CIVIL ACTION
	:	NO.
v.	:	
	:	
MILLER’S ORGANIC FARM and AMOS MILLER,	:	
	:	
Defendants.	:	

**COMPLAINT TO ENFORCE U.S. DEPARTMENT OF AGRICULTURE,
FOOD SAFETY AND INSPECTION SERVICE, SUBPOENA *DUCES TECUM***

For its Complaint, plaintiff United States of America, through the United States Attorney for the Eastern District of Pennsylvania, avers as follows:

1. This is a proceeding to enforce an administrative subpoena (the “Subpoena”) issued by the Food Safety and Inspection Service (“FSIS”). FSIS is an agency within the United States Department of Agriculture (“USDA”) that is charged with enforcing the Federal Meat Inspection Act, 21 U.S.C. § 601, et seq. (the “Meat Act”), and the Poultry Products Inspection Act, 21 U.S.C. § 451, et seq. (the “Poultry Act”), among other laws.

2. FSIS issued the Subpoena as authorized by 15 U.S.C. § 49, 21 U.S.C. § 467d (Poultry Act), 21 U.S.C. § 677 (Meat Act), and 7 C.F.R. § 2.53(a)(2)(ii) (delegating to FSIS USDA’s authority to enforce the Meat and Poultry Acts).

3. The Meat Act and the Poultry Act provide this Court with jurisdiction to enforce the Subpoena. See 21 U.S.C. § 674; 21 U.S.C. § 467c; 28 U.S.C. § 1331. A copy of the Subpoena is attached as Exhibit “A.”

4. Paul Flanagan is an Investigator within FSIS’ Office of Investigation, Enforcement, and Audit, Compliance and Investigations Division. He is assigned to FSIS’

Philadelphia Compliance Sub-Office, Northeast Region. His declaration is attached as Exhibit “B” and supports this Complaint. See Flanagan Decl. ¶ 1.

5. Defendant Miller’s Organic Farm is a farm business located at 648 Millcreek School Road, Bird-in-Hand, Pennsylvania 17505, which is in Lancaster County, Pennsylvania and is within the jurisdiction and venue of this Court. Flanagan Decl. ¶ 12.

6. Defendant Amos Miller is the owner of Miller’s Organic Farm and resides on the farm property at 648 Millcreek School Road, Bird-in-Hand, Pennsylvania 17505. Flanagan Decl. ¶ 12.

7. On information and belief, Miller’s Organic Farm: (a) operates a dairy and a retail store as a “private membership association,” which includes in-store, telephonic, and internet sales of raw milk, meat, poultry, and other products; (b) conducts custom meat and poultry slaughtering and processing operations; and (c) is processing, storing, offering for sale, and selling in person at Miller’s Organic Farm and through delivery services – as well as is offering to transport and is transporting to multiple pickup locations throughout the United States -- meat and poultry products that may require federal inspection . Flanagan Declaration, ¶ 12.

8. Unpasteurized milk and milk products contain a wide variety of harmful bacteria, including *Listeria monocytogenes*. Epidemiological studies have established a direct link between the consumption of unpasteurized milk (also known as “raw milk”) and gastrointestinal illness. Federal and state agencies have documented a long history of the risks to human health associated with the consumption of unpasteurized milk and have expressly advised consumers about the dangers of drinking unpasteurized milk. In the words of one court, “[i]t is undisputed that all types of raw milk are unsafe for human consumption and pose a significant health risk.”

Public Citizen v. Heckler, 653 F. Supp. 1229, 1241 (D.D.C. 1986), cited in United States v. Allgyer, 2012 WL 355261, at *3 (E.D. Pa. Feb. 3, 2012).

9. *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. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage, or septicemia in the newborn. 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.

10. In 2011, the United States filed an action in this Court seeking an “Administrative Warrant for Inspection” of Miller’s Organic Farm. See In the Matter of Miller’s Organic Farm, EDPA No. 11-mj-586 (Magistrate Judge Wells). In that action, the United States sought the inspection warrant on behalf of a different federal agency (the federal Food and Drug Administration, or “FDA”) and under a different statute (the federal Food Drug & Cosmetic Act, or “FDCA”) from those that are involved in this action. The United States brought the action because: (1) Amos Miller had denied an FDA investigator access to the farm (Mr. Miller had told FDA both that “only . . . members of [his] ‘food club’ [were allowed] to inspect his farm” and that he would not allow inspection without a warrant or judge’s order); and (2) the FDA had “reason to believe” that the farm was “engaged in the processing, packaging, holding and

shipment of milk in interstate commerce.” See Id. at Dkt. Entry No. 1 (Declaration attached thereto at ¶¶ 1, 6-7). Inspection later occurred after the Court issued the requested warrant. See, e.g., Id. at Dkt. Entry No. 2.

11. In March 2016, FSIS learned from the Commonwealth of Pennsylvania’s Department of Agriculture that the federal Centers for Disease Control and Prevention (“CDC”) had issued a March 18, 2016 internet posting about Miller’s Organic Farm. In that posting, the CDC stated that:

a. In 2014, an individual in Florida and an individual in California became infected with *L. mono* (listeriosis). Their ages ranged from 73 to 81. Both were hospitalized as a result, and the Florida individual died from the infection.

b. The FDA and CDC then investigated those incidents. In interviews with family members, the investigators learned that both individuals drank raw milk before getting sick, and that the Florida individual’s family purchased raw milk from Miller’s Organic Farm.

c. The FDA collected *Listeria* bacteria from the two infected individuals and, in November 2015, obtained samples of raw chocolate milk from Miller’s Organic Farm. (The samples were purchased at a raw milk conference in California.) Those raw milk samples contained *Listeria* bacteria.

d. The FDA then compared, through whole genome sequencing: (i) the *Listeria* bacteria from the two infected individuals from Florida and California; to (b) the *Listeria* bacteria found in the November 2015 raw milk samples.

f. In late January 2016, the FDA reported to CDC that: (i) the bacteria from the two individuals were “closely related genetically” to the November 2015 Miller’s Organic Farm

raw milk samples; and (ii) Miller's Organic Farm is the "likely source" of the listeriosis infections that the two individuals suffered in 2014. Flanagan Decl. ¶ 13.

12. The CDC web posting also stated: (a) "CDC is concerned that conditions may exist at [Miller's Organic Farm] that may cause further contamination of raw milk and raw dairy products distributed by this company and make people sick"; and (b) "This investigation is ongoing. CDC and state and local public health partners are continuing laboratory surveillance . . . to identify additional ill people and to interview them." Flanagan Decl. ¶ 13.

13. The CDC web post was concerning to FSIS because, at approximately the time that FSIS learned about it, FSIS also learned that Miller's Organic Farm was slaughtering, processing, and selling meat, meat food products, poultry, and poultry food products. All of this raised public health risk concerns for FSIS about possible bacterial cross-contamination from raw milk to poultry and meat and related products that are produced and sold at the farm. Flanagan Decl. ¶ 14.

14. FSIS is seeking to review and assess Miller's Organic Farm's compliance with the Meat Act and the Poultry Act.

15. Congress enacted the Meat Act and the Poultry Act to protect the health and welfare of consumers by assuring that meat and poultry products that are intended for human consumption, and that are sold, transported, or distributed in interstate commerce, are wholesome, unadulterated, and properly marked, labeled, and packaged. See 21 U.S.C. § 602 (Congressional statement of findings for Meat Act); 21 U.S.C. §§ 451, 452 (Congressional statement of findings and declaration of policy for Poultry Act). The Acts empower the

Secretary of Agriculture to regulate and inspect meat and poultry products that are intended for human consumption and that are prepared for distribution in interstate commerce.

16. The Meat Act prohibits the transportation, sale, and offering for sale, in interstate commerce, of meat and meat food products capable of use as human food unless they have been inspected and passed by the USDA.

17. Under 21 U.S.C. § 661(c) and 9 C.F.R. § 331.2, the Commonwealth of Pennsylvania has been designated as a state to which Titles I and IV of the Meat Act apply. These titles are codified at 21 U.S.C. §§ 601 to 624 and 671 to 680. Titles I and IV apply even to meat slaughter and processing operations and transactions that occur wholly *intrastate* within the Commonwealth of Pennsylvania – and to the persons engaged in them – to the same extent and in the same manner as if the operations and transactions were conducted in or for interstate commerce.

18. Among the provisions of Title I and Title IV of the Meat Act that apply even to *intrastate* operations and transactions in the Commonwealth of Pennsylvania are provisions:

- a. authorizing federal inspectors to conduct ante-mortem inspection of livestock and post-mortem inspection of their carcasses and the meat food products produced therefrom, to prevent the entry into, or flow of movement within, commerce of – or the burdening of commerce by – any adulterated meat or meat food product capable of use as a human food, 21 U.S.C. §§ 604, 606;
- b. restricting persons from selling, transporting, offering for sale or transportation, or receiving for transportation, in commerce, any meat

products required to be inspected under the Meat Act unless they have been so inspected and passed inspection, 21 U.S.C. § 610(c)(2);

- c. requiring compliance with Meat Act requirements such as maintaining a sanitary facility -- even by entities that are exempt from federal inspection under certain circumstances (such as slaughter for “custom use”), 21 U.S.C. § 623(a);
- d. authorizing USDA: (i) to have access, at all reasonable times, to places of business; (ii) to have the opportunity to examine the business facilities, inventory and records; (iii) to copy all such records documenting the processing, sale, and transport of meat and meat food products; and (iv) to take reasonable samples of inventory upon payment of fair market value, 21 U.S.C. § 642; and
- e. requiring each business subject to the Meat Act to provide USDA inspectors with access to facilities and records documenting the processing, sale, and transport of meat and meat food products. 21 U.S.C. § 642.

19. The Poultry Act prohibits the transportation, selling, and offering for sale, in interstate commerce, of poultry and poultry products capable of use as human food unless they have been inspected and passed by the USDA. 21 U.S.C. § 458(a)(2).

20. Under 21 U.S.C. § 454(c)(1) and 9 C.F.R. § 381.221, the Commonwealth of Pennsylvania has been designated as a state to which Sections 451-453, 455-459, and 461-467d of the Poultry Act apply. These sections of the Poultry Act apply even to poultry operations and transactions that occur wholly *intrastate* within the Commonwealth of Pennsylvania – and to the

persons engaged in them – to the same extent and in the same manner as if such operations and transactions were conducted in or for interstate commerce.

21. Among Sections 451-453, 455-459, and 461-467d of the Poultry Act, which apply even to *intrastate* operations and transactions in the Commonwealth of Pennsylvania, are provisions:

- a. authorizing federal inspectors to conduct ante-mortem inspection of poultry and post-mortem inspection of their carcasses and the poultry food products produced therefrom, to prevent the entry into, or flow of movement within, commerce of – or the burdening of commerce by – any adulterated poultry product capable of use as a human food, 21 U.S.C. §§ 455(a), (b);
- b. restricting persons from selling, transporting, offering for sale or transportation, or receiving for transportation, in commerce, any poultry food products required to be inspected under the Poultry Act unless they have been so inspected and passed inspection, 21 U.S.C. § 458(a)(2)(B);
- c. requiring compliance with Poultry Act requirements such as maintaining a sanitary facility -- even by entities that are exempt from federal inspection under certain circumstances (such as slaughter for “custom use” or retail sale), 21 U.S.C. § 465;
- d. authorizing USDA: (i) to have access, at all reasonable times, to places of business; (ii) to have the opportunity to examine the business facilities, inventory and records; (iii) to copy all such records documenting the processing, sale, and transport of poultry and poultry food products; and

(iv) to take reasonable samples of inventory upon payment of fair market value, 21 U.S.C. § 460(b); and

- e. requiring each business subject to the Poultry Act to provide USDA inspectors with access to facilities and records documenting the processing, sale, and transport of poultry and poultry products. 21 U.S.C. § 460.

22. Defendants Miller's Organic Farm and Amos Miller are in possession, custody, or control of books, records, and other documents – and/or have knowledge -- relating to whether meat and poultry food products being offered for sale at Miller's Organic Farm were:

(a) required to be federally inspected because not produced in accordance with statutory requirements for custom exemption; and (b) produced, stored, and transported in a manner to prevent adulteration. The Meat Act and the Poultry Act require Miller's Organic Farm to maintain these records and to give FSIS access to them and to the Miller's Organic Farm facilities. Flanagan Declaration, ¶¶ 5-9, 18, 23.

23. From March 22, 2016 through May 2016, FSIS unsuccessfully tried to obtain access to Miller's Organic Farm's facilities and business records without having to issue a subpoena. FSIS sought such access in order to conduct a verification review. A verification review seeks to ensure that subject facilities are in compliance with the Meat Act, the Poultry Act, and the regulations under those statutes that relate to sanitation, recordkeeping, labeling, custom exemption, retail exemption, and other requirements. Verification reviews may:

(a) involve FSIS veterinarians, consumer safety officers, investigators, and other program employees; and (b) include an examination of sanitation and facilities; water supply; sewage and waste disposal; pest control; inedible material control; marking and labeling; recordkeeping; and

compliance with custom exemption requirements. Such reviews fulfill the agency's mission to ensure that meat and poultry products intended for human consumption and sale and distribution in commerce are safe, wholesome, not adulterated, and correctly marked, labeled, and packaged. Flanagan Decl. ¶¶ 8-9, 15-29.

24. Mr. Miller denied FSIS' requested access to Miller's Organic Farm's facilities and business records. Mr. Miller stated that he would not provide such access absent a court warrant or order. Flanagan Decl. ¶ 16, 19-21, 24-30.

25. The USDA-FSIS Administrator issued the Subpoena on April 4, 2016, and FSIS Investigator Flanagan served the Subpoena by personal delivery to Amos Miller at Miller's Organic Farm on April 13, 2016. Flanagan Decl. ¶¶ 17-19, 22.

26. The Subpoena required Mr. Miller and Miller's Organic Farm to provide FSIS with access to: (a) Miller's Organic Farm's facilities, particularly buildings and facilities "used for the slaughter of livestock, or the handling, storage, transportation of meat or poultry products, including all compartments, rooms and spaces, including trailers, product containers, outbuildings of any kind, and/or storage area(s) located thereon"; and (b) certain documents, particularly "business records . . . pertaining to meat and poultry products produced, received, handled, transported and sold, for the period January 1, 2016 to present," including categories of documents that the subpoena described in greater detail. Flanagan Decl. ¶ 17 & Exhibit "A" hereto (Subpoena).

27. Invoking protection under the United States Constitution, on grounds that Miller's Organic Farm sells its meat and poultry products as a private membership association that is not subject to the Meat Act, the Poultry Act, and USDA-FSIS jurisdiction, Mr. Miller refused to

comply with the Subpoena and to provide FSIS with access to Miller's Organic Farm's facilities and documents absent a court warrant or order requiring compliance. Flanagan Decl. ¶¶ 19-21, 24-30 & Exhibits "3," "4," and "5" thereto.

28. The books, papers, records, and other data and information that the Subpoena seeks are not in the USDA's possession, custody, or control. Flanagan Decl. ¶ 33.

29. The access to Miller's Organic Farm's facilities and documents that the Subpoena seeks is for a legitimate purpose because such access is relevant to, and can reasonably be expected to aid, FSIS' review and surveillance of Miller's Organic Farm's compliance with the Meat Act and the Poultry Act. Flanagan Decl. ¶ 32.

30. The Subpoena was issued and served in accordance with FSIS administrative procedures and 7 C.F.R. § 1.29. Flanagan Decl. ¶¶ 18, 22 & Exhibit "A" hereto (Subpoena) at p. 3.

31. The United States has not previously applied to the Court to enforce the Subpoena.

32. It is the practice of this Court to proceed by Complaint and Order to Show Cause in procedurally related Internal Revenue Service administrative summons enforcement matters. See Local Rule of Civil Procedure 4.1.2 (E.D. Pa.).

33. Concurrently with the filing of this Complaint, the United States is filing a memorandum of law setting forth the legal grounds supporting enforcement of the Subpoena.

WHEREFORE, plaintiff United States of America respectfully asks this Court to:

Enter an Order directing defendants Amos Miller and Miller's Organic Farm to show cause why they should not be required to comply with and obey the Subpoena;

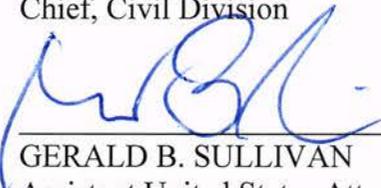
Enter an Order directing defendants Amos Miller and Miller's Organic Farm to obey the Subpoena by: (a) producing to FSIS the records requested in the Subpoena, at such time and place as FSIS may fix; and (b) granting FSIS, as requested in the Subpoena, access to Miller's Organic Farm's buildings and facilities; and

Render such other and further relief as is just and proper.

ZANE DAVID MEMEGER
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