



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

UNITED STATES OF AMERICA,

Plaintiff,

v.

MILLER'S ORGANIC FARM and
AMOS MILLER,

Defendants.

A TRUE COPY CERTIFIED TO FROM THE RECORD
DATED: 6-3-16
ATTEST: [Signature]
CIVIL ACTION
NO. 16-cv- [Signature]
DEPUTY CLERK, UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

16 2732

**MEMORANDUM OF LAW SUPPORTING COMPLAINT
TO ENFORCE ADMINISTRATIVE SUBPOENA DUCES TECUM**

Plaintiff United States of America, on behalf of the United States Department of Agriculture ("USDA"), respectfully submits this memorandum of law in support of its Complaint in this action. The Complaint seeks to enforce the USDA's April 2016 administrative subpoena to Miller's Organic Farm and its owner and operator, Amos Miller, because these defendants refused to comply with the subpoena. Authority to enforce the subpoena in this action exists under Section 9 of the Federal Trade Commission Act, 15 U.S.C. § 49, as incorporated by Section 407 of the Federal Meat Inspection Act (the "Meat Act"), 21 U.S.C. § 677, and Section 22 of the Poultry Products Inspection Act (the "Poultry Act"), 21 U.S.C. § 467d.

BACKGROUND

As set forth more fully in the Complaint, the Secretary of Agriculture (the "Secretary") is reviewing Miller's Organic Farm and Mr. Miller to assess and ensure their compliance with USDA laws and regulations. See Complaint, Exhibit "B" (Declaration of Paul Flanagan), at ¶ 13-33. The Food Safety and Inspection Service ("FSIS"), a public health agency within the USDA that is charged with ensuring compliance with the Meat Act and the Poultry Act, is

performing that review for the Secretary. Id. ¶¶ 1, 4, 12-33. The review particularly concerns whether meat, meat products, poultry, and poultry products are being handled at -- and distributed from -- Miller's Organic Farm in compliance with the Meat Act, as amended, 21 U.S.C. § 601 et seq.; the Poultry Act, as amended, 21 U.S.C. § 451, et seq.; and the regulations issued under those statutes, 9 C.F.R. §§ 301 et seq. and 381 et seq.¹ Flanagan Decl. ¶¶ 4-11, 14-19, 23, 31-32.

Miller's Organic Farm is a Lancaster County, Pennsylvania farm that includes: (1) a dairy; (2) meat and poultry slaughtering operations; and (3) a retail store. Retail sales (including of raw milk, meat, and poultry products) are made to purchasers at and from the farm store not only in-person but also by telephone and through a web site. See Flanagan Decl. ¶ 12; see also, e.g.: (1) <http://www.millersorganicfarm.com/> (Miller's Organic Farm website); (2) <http://www.myhealthyfoodclub.com/assets/images/Docs/farm-food-price-list.pdf> (May 2016 farm price list and ordering information) (downloaded on June 1, 2016 and attached to Flanagan Decl. as Exhibit "1"). The farm ships the meat, poultry, and other products that are ordered and sold by telephone or internet either directly to purchasers' addresses through FedEx or to multiple pick-up locations throughout the United States. Flanagan Dec. ¶ 12 & Exhibit "1" thereto (May 2016 farm price list, at p. 2).

¹ Congress enacted the Meat Act and the Poultry Act to protect the health and welfare of consumers by assuring that meat and poultry food products that are intended for human consumption -- and that are sold, transported, or distributed in interstate commerce -- are wholesome, not adulterated, and properly marked, labeled, and packaged. See 21 U.S.C. §§ 451, 602. The statutes contain prohibited acts provisions that strictly proscribe, among other things: (1) the slaughter or preparation of cattle, sheep, swine, goats, poultry, and other species, carcasses, and parts except in strict compliance with USDA laws; and (2) the sale, transport, or offer for sale or transportation adulterated or misbranded carcasses, parts, or meat or poultry products. See 21 U.S.C. §§ 458, 610. The Meat Act and Poultry Act authorize civil sanctions to enforce, prevent, and restrain violations of the Acts, and also provide for criminal penalties. See 21 U.S.C. §§ 461, 467c, 674, 676.

In his discussions and correspondence with FSIS, and consistent with publications on his farm's website, Mr. Miller has stated that Miller's Organic Farm operates as a "private membership association" and that all of its sales are made only: (1) to its members; and (2) after they pay a one-time \$35 membership fee and sign a membership agreement. See Flanagan Decl. ¶¶ 16, 19-21, 24-25, 28-30 & Exhibits "1," "3," "4," and "5" thereto; see also <http://www.myhealthyfoodclub.com/assets/images/Docs/MillersOrganicFarmMembershipContract.pdf> (internet version of Miller's Organic Farm membership agreement). The terms of that agreement include the following:

I understand that, since the Association is protected by the 1st and 14th Amendments to the U.S. Constitution, it is outside the jurisdiction and authority of Federal and State Agencies and Authorities concerning any and all complaints or grievances against the Association, any Trustee(s), members or other staff persons. All rights of complaint or grievances will be settled by an Association Committee My activities within the Association are a private matter that I refuse to share with State Medical Board(s), the FDA, FTC, State Milk Board(s), USDA, Agriculture Board(s) and any other governmental agency without my expressed specific permission. All records and documents remain as property of the Association, even if I receive a copy of them.

See Flanagan Decl. ¶ 29 and Exhibit "5" thereto at p. 1-2.

Unpasteurized milk and milk products contain a wide variety of harmful bacteria, including *Listeria monocytogenes* ("*L. mono*"). Epidemiological studies have established a direct link between the consumption of unpasteurized 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.

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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).

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. See, e.g., <http://vm.cfsan.fda.gov/~mow/chap6.html> (FDA's Center for Food Safety & Applied Nutrition, Foodborne Pathogenic Microorganisms and Natural Toxins Handbook, Section on "*Listeria monocytogenes*").

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). The United States sought the inspection warrant on behalf of a different federal agency (the Food and Drug Administration, or "FDA") and under a different statute (the federal Food Drug & Cosmetic Act, or "FDCA") from those that are at issue in this case. The United States did so because: (1) Amos Miller had denied an FDA investigator access to his 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 (attached Declaration at ¶¶ 1, 6-7). Inspection later occurred after Magistrate Judge Wells issued the requested warrant. See, e.g., Id., Dkt. Entry No. 2.

FSIS began to focus on Miller’s Organic Farm in March 2016 based on a March 18, 2016 internet posting by the federal Centers for Disease Control and Prevention (“CDC”). Flanagan Decl. ¶ 13 & Exhibit “2” thereto. That CDC posting stated in part 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 the CDC then investigated the two 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.

e. The FDA compared, through whole genome sequencing: (i) the *Listeria* bacteria from the two infected individuals from California and Florida; to (ii) 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. See Flanagan Decl. ¶ 13 & Exhibit “2” thereto; see also <http://www.cdc.gov/listeria/outbreaks/raw-milk-03-16/> (March 18, 2016 CDC web notice).

The CDC’s web post added that: (1) “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 (2) “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.” Id.

The CDC’s web post raised concerns for FSIS -- in light of the agency’s mission under the Meat Act and the Poultry Act -- when, at about the same time, 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.

In follow-up, FSIS attempted to conduct what is known as a “verification review” at Miller’s Organic Farm. By way of legal background, even if Miller’s Organic Farm were somehow able to establish that it should be exempt from USDA daily inspection and approval requirements that apply to what are known “federal establishments,” the farm’s facilities that are involved with slaughtering and processing of meat, meat products, poultry, and poultry products would still be (and are) subject to periodic FSIS inspection and records reviews and inquiries. These verification reviews seek 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. See

Flanagan Decl. ¶¶ 5-9, 15; see also 21 U.S.C. § 642 (providing that facilities must “upon notice by a duly authorized representative of the Secretary, afford such representative access to their places of business and opportunity to examine the facilities, inventory, and records thereof”); 21 U.S.C. § 460; 9 C.F.R. § 320.4.

Verification reviews may involve FSIS veterinarians, consumer safety officers, investigators, and other program employees. Further, the reviews may 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. Flanagan Decl. ¶ 8. Such reviews fulfill the agency’s mission to ensure that meat and poultry food products that are intended for human consumption -- and for sale, transportation, or distribution in interstate commerce -- are safe, wholesome, not adulterated, and correctly marked, labeled, and packaged.² Id. ¶¶ 4, 9-11. Congress has authorized such reviews even for wholly Pennsylvania intrastate meat and poultry slaughtering and processing operations (i.e., where the resulting meat and poultry products never leave the Commonwealth of Pennsylvania). See Complaint, ¶¶ 17-21 (summarizing law).

When FSIS attempted to conduct a verification review at Miller’s Organic Farm on March 22, 2016, Mr. Miller denied FSIS access to his farm facilities and records because he characterized the farm as being a “private membership association” and thus non-public in nature. He directed FSIS to return only with a warrant. Flanagan Decl. ¶¶ 15-16.

On April 4, 2016, the FSIS Administrator issued a subpoena *duces tecum* under Section 406 of the Meat Act, 21 U.S.C. § 677, and Section 22 of the Poultry Act, 21 U.S.C. § 467d.

² When verification reviews show unsanitary conditions or other noncompliance, FSIS applies its authorities under the Meat Act and the Poultry Act to control and detain adulterated and misbranded product. See 21 U.S.C. §§ 467A, 672. See also Flanagan Decl. ¶ 9.

Flanagan Decl. ¶¶ 17, 18, 22; see also Complaint, Exhibit “A” thereto (Subpoena) at p. 3. The subpoena commanded Mr. Miller and Miller’s Organic Farm to provide FSIS access to relevant farm facilities and business records, as required by Section 202 of the Meat Act, 21 U.S.C. § 642, and Section 11 of the Poultry Act, 21 U.S.C. § 460.

On April 13, 2016, an FSIS investigator, Mr. Flanagan, served the subpoena on Mr. Miller by hand delivery. Flanagan Decl., ¶¶ 19-20, 22. In stating to the investigator on that date that he would not comply with the subpoena, Mr. Miller again invoked his farm’s “private,” non-public character as a shield against FSIS enforcement of the Meat Act and the Poultry Act. *Id.* ¶¶ 19-21. He made similar arguments in follow-up written and oral communications with FSIS in April and May 2016, and he continued to deny access to FSIS absent: (1) a court order or warrant; and (2) FSIS investigators signing a copy of his farm’s private membership agreement. Flanagan Decl. ¶¶ 24-25, 27-29 & Exhibits “3,” “4,” and “5” thereto.

As a result of this history, and Mr. Miller’s contentions that the USDA lacks any jurisdictional and constitutional basis to review the Miller’s Organic Farm facilities and records, FSIS concluded that, without a court order, Mr. Miller would not permit FSIS to enter his property to conduct a verification review. FSIS was therefore forced to initiate this enforcement action. Flanagan Decl. ¶ 31.

ARGUMENT

DEFENDANTS SHOULD BE ORDERED TO COMPLY WITH THE SUBPOENA.

A. The USDA’s administrative subpoena should be enforced.

Subpoenas that FSIS issues to enforce the Meat Act and the Poultry Act are not self-enforcing. Rather, FSIS must obtain authority to enforce them from the federal district court. Such an enforcement action, as here, is a summary proceeding in which the Court plays a

“strictly limited role.” See 21 U.S.C. §§ 467c, 467d, 674, 677; United States v. O’Neill, 619 F.2d 222, 228 (3d Cir. 1980); United States v. Philadelphia Hous. Auth., 2011 WL 382765, at *1 (E.D. Pa. Feb. 4, 2011); EEOC v. Sunoco, Inc., 2009 WL 197555, at *2 (E.D. Pa. Jan. 26, 2009); United States v. Nour Halal Meat Distrib., 505 F. Supp. 2d 275, 279 (W.D. Pa. 2007).

In determining whether to enforce administrative subpoenas, the courts have generally reviewed the criteria that apply to judicial enforcement of Internal Revenue Service summonses, as set forth in United States v. Powell, 379 U.S. 48, 57-58 (1964). See EEOC v. Kronos, Inc., 620 F.2d 287 (3d Cir. 2010); U.S. v. Philadelphia Hous. Auth., 2011 WL 382765, at *1. Under these criteria, which are embodied in this Court’s Local Rule of Civil Procedure 4.1.2, the USDA here “must show [1] that the investigation will be conducted pursuant to a legitimate purpose, [2] that the inquiry may be relevant to the purpose, [3] that the information sought is not already within the . . . [Secretary’s] possession, and [4] that the administrative steps required . . . have been followed[.]” Powell, 379 U.S. at 57-58; U.S. v. Philadelphia Hous. Auth., 2011 WL 382765, at *1 (rephrasing these criteria as “(1) the subpoena is within the statutory authority of the agency; (2) the information sought is reasonably relevant to the inquiry; and (3) the demand is not unreasonably broad or burdensome”), quoting United States v. Westinghouse Elec. Corp., 788 F.2d 164, 166 (3d Cir. 1986); accord Chao v. Community Trust Co., 474 F.3d 75, 79 (3d Cir. Mar. 7, 2007) (characterizing this last criterion as: “the demand for production must not be too indefinite”). Such a government showing constitutes a *prima facie* case for enforcement of the subpoena. See Nour Halal Meat Distrib., 505 F. Supp. 2d at 279.

Once the government makes this showing, the opposing party bears the burden of establishing that the subpoena should not be enforced. See Powell, 379 U.S. at 58; United States v. LaSalle Nat’l Bank, 437 U.S. 298, 315 (1978); U.S. v. Philadelphia Hous. Auth., 2011 WL

382765, at *3 (“The burden of demonstrating that a demand is unreasonable falls upon the subpoenaed party. The burden is not easily met when the agency inquiry ‘is authorized by law and the materials sought are relevant to the inquiry’” because “[a]gencies are accorded ‘extreme breadth’ in conducting their investigation”) (citations omitted); Nour Halal Meat Distrib., 505 F. Supp. 2d at 280-81 (a “heavy” “burden . . . shifts to Defendants to show” by affidavit rather than merely by legal conclusions and memoranda “that the Subpoena is overly broad, burdensome, or that its enforcement would constitute an abuse of the court’s process” such as “to harass the respondent or to put pressure on him to settle a collateral dispute”) (also stating that “[i]f Defendants fail to carry their burden, it is the Court’s duty to enforce the terms of the Subpoena”), citing FTC v. Standard Am., Inc., 306 F.2d 231, 234-35 (3d Cir. 1962).

Each of the Powell criteria is satisfied here.

First, FSIS seeks the records and access for a legitimate purpose. That purpose is FSIS’ effort to ascertain whether Miller’s Organic Farm is in compliance with the Meat Act, the Poultry Act, and applicable related regulations governing the safe handling of poultry and meat products. Flanagan Decl., ¶¶ 14-15, 17-19, 32. FSIS issued the subpoena within its statutory and regulatory authority. As the subpoena states, it was issued under Section 9 of the Federal Trade Commission Act, 15 U.S.C. § 49, which also authorizes enforcement by this Court. Section 9 applies to the Secretary’s jurisdiction, powers, and duties in enforcing the provisions of the Meat Act and the Poultry Act. See 21 U.S.C. § 677; 21 U.S.C. § 467d; see also Flanagan Decl. ¶¶ 18, 22; Complaint, Exhibit “A” thereto (Subpoena) at p. 3. This includes USDA authority to issue administrative subpoenas to obtain information and records that are necessary to the efficient administration and enforcement of the Acts. See 21 U.S.C. §§ 467d, 677.

Second, the kinds of records and access that FSIS seeks are “relevant” to the agency’s legitimate purpose in seeking them. As discussed above, even “custom exempt” slaughtering and meat processing facilities must comply with sanitation, recordkeeping, and other USDA regulations. FSIS is charged with enforcing these requirements, and as part of its mission is entitled to inspect Miller’s Organic Farm and its records to ensure compliance. Defendants’ refusal to permit access to Miller’s Organic Farm or to provide the requested records necessitated the April 4, 2016 issuance of the subpoena and the initiation of this proceeding to enforce it. Flanagan Decl. ¶¶ 15-31. Access to Miller’s Organic Farm will enable FSIS to examine the farm’s facilities to ensure that they are in compliance with sanitation, custom exempt, and other requirements, and to examine the farm’s records to determine whether Miller’s is in compliance with recordkeeping, custom exempt, and other requirements and applicable regulations. Flanagan Dec. ¶¶ 8, 17-19, 23, 31-32.

Third, FSIS has never been afforded access to Miller’s Organic Farm and is not in possession of the documents that that the subpoena seeks and that defendants have failed to make available to FSIS. Flanagan Decl. ¶ 33.

Fourth, FSIS has taken all administrative steps necessary for the issuance of the subpoena. Investigator Flanagan served the subpoena on Amos Miller by hand on April 13, 2016, under 7 C.F.R. § 1.29. Flanagan Decl. ¶ 22.

Additionally, the subpoena request for access to Miller’s Organic Farm’s facilities and records is not unreasonably broad or burdensome. Rather, consistent with FSIS’ public health and safety mission, and the concerns that came to the agency’s attention in March 2016, the subpoena states that: (1) physical access is required for 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 (2) document access is required for “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. See Flanagan Decl. ¶¶ 17-18; Complaint, Exh. “A” (Subpoena) at pp. 1-3.

Because the government has satisfied the Powell criteria and thus made out a *prima facie* case for subpoena enforcement, defendants bear the burden of establishing that enforcement would constitute an abuse of the Court’s process. Powell, 379 U.S. at 58. To date, defendants have offered no defensible reason for their failure to comply with the subpoena, and they are not able to meet their burden.

B. Defendants cannot meet their Powell burden.

1. “Private membership association” status does not shield defendants from FSIS oversight.

Based on his various communications with the government and the information published on his farm’s website, Mr. Miller will likely contend that Miller’s Organic Farm’s status as a private membership association places the farm, and him, beyond the jurisdiction of the Meat Act, the Poultry Act, the USDA, FSIS, and the Court. See Flanagan Decl. ¶¶ 16, 19-21, 24-30 & Exhibits “3,” “4,” and “5” thereto.

For several reasons, however, Mr. Miller and his farm cannot evade the law by forming a contractual relationship with members of his private membership association.

First, the Meat Act and the Poultry Act do not recognize an exception -- based on the nature of the contractual relationship between producer and end user -- either to the USDA’s/FSIS’ inspection and review authority or to these Acts’ clear prohibitions on the sale of

adulterated or misbranded meat and poultry products. See generally Wedgewood Village Pharmacy, Inc. v. United States, 421 F.3d 263, 273 (3d Cir. 2005) (holding that FDA has authority to inspect to determine if it has jurisdiction over establishment, and finding that FDA does not need to rely on firm's claim that it is excepted from FDA's inspection authority). Arguments for such an exception in the context of the FDCA have been advanced and rejected by several district courts.

For example, in United States v. Allgyer, 2012 WL 355261 (E.D. Pa. Feb. 3, 2012), Judge Lawrence Stengel of this Court granted summary judgment in favor of the government against the owner of a Lancaster County farm that distributed raw milk in interstate commerce and had resisted FDA inspection. Although the owner invoked constitutional protections based on his milk buyers being limited to members of his private membership cow sharing group, Judge Stengel rejected this defense and stressed:

The contract between [the owner] and persons entering into a cow sharing agreement is merely a subterfuge to create a transaction disguised as a sale of raw milk to consumers. The practical result of the arrangement is that consumers pay money to [the owner] and receive raw milk, which is transported across state lines and left at a 'drop point.' As such, despite any artful language, the agreement involves the transfer of raw milk for consideration, which constitutes a sale and is lawfully regulated by the FDA.

Allgyer, 2012 WL 355261, at *1, 4-5 & n. 15. See also, e.g. United States v. Cole, 84 F. Supp. 3d 1159, 1170 (D. Or. 2015) (characterizing "private membership association" as an attempt to "flout any injunction" to enforce the FDCA); United States v. Travia, 180 F. Supp. 2d 115, 120-21 (D.D.C. 2001) (rejecting argument that the FDCA did not apply to "private behavior"). Accord Lytle v. HHS, 612 Fed. Appx. 861 (8th Cir. Aug. 21, 2015) ("That a product is sold

through a PMA [private membership association] does not exempt it from the application of this [FDCA] provision”).³

Second, an individual cannot exempt himself from the reach of federal law through the use of private contracts. Such attempts run afoul of well-established law that a contract entered in violation of federal statutory or regulatory law is unenforceable. See, e.g., United Paperworkers Int’l Union, AFL-CIO v. Misco, Inc., 484 U.S. 29, 42 (1987).

Third, wholly without merit or foundation is any argument that Mr. Miller’s or his farm’s conduct is: (1) “non-commercial” or otherwise exempt from regulation under the Meat Act and the Poultry Act because the conduct has a *de minimis* impact on interstate commerce or is wholly intrastate (as noted in the Complaint at ¶¶ 17-21, the Meat Act and Poultry Act in relevant part apply even to wholly Pennsylvania intrastate slaughtering and processing activity); and (2) somehow outside the reach of the federal government’s Commerce Clause authority.

The Constitution grants Congress broad authority to “regulate Commerce . . . among the several States,” U.S. Const. art. I, § 8, cl. 3. Congress may “regulate the *channels* of interstate commerce”; it may “regulate and protect the *instrumentalities* of interstate commerce, and persons or things in interstate commerce”; and it may “regulate activities that substantially affect interstate commerce.” Gonzales v. Raich, 545 U.S. 1, 16-17 (2005) (italics added); United States v. Regenerative Sciences, LLC, 741 F.3d 1314, 1320 (D.C. Cir. 2014). The Supreme Court has instructed that courts “need not determine whether [the] activities, taken in the aggregate,

³ See generally Farm-to-Consumer Legal Def. Fund v. Wisconsin Dep’t of Agric., Trade and Consumer Prot., 855 N.W.2d 720, ¶ 41 (Wis. Ct. App. 2014) (finding that contractual arrangement via private membership association “was created for the sole purpose of producing and selling unpasteurized milk to members [of the association], in violation of [state law]” and was thus invalid attempt to facilitate illegal sale of unpasteurized milk to consumers); Meadowsweet Dairy, LLC v. Hooker, 71 A.D.3d 1266, 1269 (N.Y. App. Div. 2010) (private membership association created to provide members with shares in daily farm in order to receive unpasteurized milk as “dividends” held subject to regulations over adulterated and misbranded food because it was “purposely designed to avoid cash sales of dairy products in an attempt to circumvent” state law).

substantially affect interstate commerce in fact, but only whether a ‘rational basis’ exists for so concluding” that there is a substantial effect. Gonzales, 545 U.S. at 22. Indeed, “when a general regulatory statute bears a substantial relation to commerce, the *de minimis* character of individual instances arising under that statute is of no consequence.” Id. at 17 (internal quotations and citations omitted).

There is no exception to the commerce power for the sorts of transactions between “private” individuals that Mr. Miller has described to FSIS. Nor is there an exception for activities that only incidentally affect commerce. Rather, Congress’ commerce power is expansive, even permitting government regulation of products that are produced and consumed wholly within one’s home -- as long as there is some nexus to interstate commerce. See generally Wickard v. Filburn, 317 U.S. 111 (1942) (holding commerce power authorizes Congress to regulate farmer’s production of wheat intended solely for his own consumption and not placed into interstate commerce); see also United States v. Regenerative Sciences, LLC, 741 F.3d 1314, 1320-21 (D.C. Cir. 2014) (use of single component shipped in interstate commerce is sufficient to trigger FDCA provisions). Indeed, even the “transportation of one’s own goods from state to state is interstate commerce.” United States v. Hill, 248 U.S. 420, 424 (1919). See generally Daily v. Veneman, 2002 WL 31780191, at *4 (6th Cir. Dec. 3, 2002) (affirming dismissal of State of Ohio’s Commerce Clause challenge to Meat Act and Poultry Act, and stating: “Congress’s power to regulate things in interstate commerce surely includes the power to ensure that a commodity does not become a thing in interstate commerce; and meat and poultry products that are sold in intrastate commerce, when considered in the aggregate, have a substantial [e]ffect on interstate commerce”)

The Meat Act and the Poultry Act are proper exercises of Congress' commerce power.⁴ See, e.g., Pittsburgh Melting Co. v. Totten, 248 U.S. 1, 8 (1918) ("The enactment of the [Meat Act] was within the power of Congress in order to prevent interstate or foreign shipments of impure or adulterated meat food products"). In amending the Meat Act and the Poultry Act, Congress expressly found that -- because of the nature of meat, meat food products, poultry, and poultry products -- "all articles and" animals/poultry "which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary [of Agriculture]. . . as contemplated by this chapter [is] appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers." 21 U.S.C. § 451, 602. See generally United States v. Mullens, 583 F.2d 134, 139 (5th Cir. 1978) ("The purpose of the Meat Act . . . as amended . . . is to ensure a high level of cleanliness and safety in meat products. Such a purpose is certainly legitimate and within the power of the federal Government under the commerce clause").

The at-issue conduct of Mr. Miller and Miller's Organic Farm is indisputably commercial, is connected to commerce (both intrastate and interstate), and falls squarely under the Meat Act and the Poultry Act. For example:

- in addition to in-person sales at Miller's Organic Farm, the farm's web page provides instructions on how the farm's raw milk, poultry, and meat products can

⁴ See generally 35A Am. Jur. Food § 5 & nn. 1-2, 4-5, 8-9 (Feb. 2016) ("The authority of the federal government to regulate food rests upon the power of Congress to regulate interstate commerce. Congress may enact federal legislation to keep interstate commerce free from deleterious, adulterated, and misbranded articles of specified types to advance the public health and safety and has done so by such legislation as the [Poultry Act and the Meat Act]. . . . These acts and similar legislation insure that products desired by consumers are made available to them in a form and manner consistent with the public health and welfare. . . . The Secretary of Agriculture is authorized to promulgate regulations pursuant to these [Acts].") (footnotes and citations omitted).

be ordered by telephone, paid for, and then shipped by FedEx to purchasers' addresses. See Flanagan Decl. ¶ 12 and Exhibit "1" thereto.

- Miller's Organic Farm transports such products for sale to pick-up locations throughout the United States. See Flanagan Decl. ¶ 12 and Exhibit "1" thereto.
- As the March 18, 2016 CDC web posting stated, Miller's raw milk samples were purchased in 2015 at a raw milk conference in California. See Flanagan Decl. ¶ 13 & Exhibit "2" thereto.

Any Miller's Organic Farm misbranded or adulterated meat or poultry products would be illicit products that the Meat Act and the Poultry Act would prohibit from moving through commerce. See, e.g., Hipolite Egg Co. v. United States, 220 U.S. 45, 57 (1911) ("We are dealing, it must be remembered with illicit articles, -- articles which the law seeks to keep out of commerce"). See generally Allgyer, 2012 WL 355261, at *1, 4-5 & n. 15 ("The practical result of the [private membership] arrangement is that consumers pay money to [the owner] and receive raw milk, which is transported across state lines and left at a 'drop point.' As such, despite any artful language, the agreement involves the transfer of raw milk for consideration, which constitutes a sale and is lawfully regulated by the FDA").

In sum, because Mr. Miller has chosen to operate in a pervasively regulated industry (selling meat and poultry products), he is subject to the Meat Act and the Poultry Act, including their inspection and record-keeping requirements. See United States v. Pine Valley Poultry Distributors Corp., 187 F. Supp. 455, 456-57 (S.D.N.Y. 1960) (in Poultry Act proceeding, stating that: "The power of Congress to require those engaged in a business affected with a public interest to keep records subject to inspection by an administrator in order to secure enforcement

of the law is not open to constitutional objection. Thus, the books and records so kept are not private papers or records, but assume the characteristics of public or quasi-public documents”).

2. Enforcement of FSIS’ subpoena does not infringe defendants’ Constitutional rights.

Mr. Miller has suggested that subpoena enforcement would violate his First Amendment rights to association and free speech, as well as possibly his Fourth Amendment rights protecting him from unreasonable searches and seizures. See Flanagan Decl. ¶¶ 20-21, 25, 28-29 & Exhibits “3,” “4,” and “5” thereto.

Mr. Miller and his farm have no such First Amendment rights. Freedom of speech and association does not include freedom to violate the USDA facility and document review provisions of the Meat Act and the Poultry Act. To the extent that Mr. Miller complains that these Acts impair his private membership association contract, such a result is constitutionally permissible because “Congress . . . undeniably[] has authority to pass legislation pertinent to any of the powers conferred by the Constitution however it may operate collaterally or incidentally to impair or destroy the obligation of private contracts.” Cont’l Illinois Nat’l Bank & Trust Co. of Chicago v. Chicago, R.I. & P. Ry. Co., 294 U.S. 648, 680 (1935).

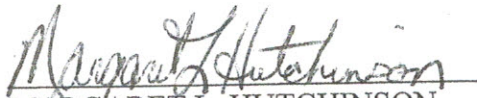
This is not to say that the First Amendment does not provide protection to Mr. Miller for embracing and advocating alternative food. To the contrary, and subject to limitations on commercial speech that is untruthful or misleading, “[t]he First Amendment protects expression, be it of the popular variety or not. . . . And the fact that an idea may be embraced and advocated by increasing numbers of people is all the more reason to protect the First Amendment rights of those who wish to voice a different view.” Boy Scouts of America v. Dale, 530 U.S. 640, 660 (2000), cited in United States v. 2035 Inc., 2015 WL 213170, at *2 (D.S.D. Jan. 14, 2015).

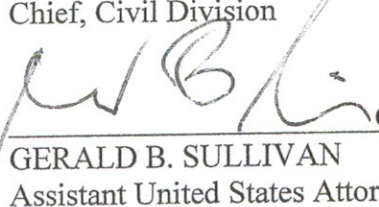
CONCLUSION

For all of the foregoing reasons, the Court should direct defendants Miller's Organic Farm and its owner, Amos Miller, to comply with FSIS' administrative subpoena without further delay.

Respectfully submitted,

ZANE DAVID MEMEGER
United States Attorney


MARGARET L. HUTCHINSON
Assistant United States Attorney
Chief, Civil Division

 GBS3408
GERALD B. SULLIVAN
Assistant United States Attorney
Attorney I.D. No. 57300
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106-4476
(215) 861-8786
(215) 861-8618 (fax)

Attorneys for the United States of America

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OF COUNSEL:

Tracey Manoff, Attorney
Office of the General Counsel
U.S. Department of Agriculture
14th & Independence Ave., S.W.
South Building
Washington, D.C. 20250-1400