BEFORE THE UNITED STATES DEPARTMENT OF LABOR
ADMINISTRATIVE REVIEW BOARD

CRAIG WATTS,

Complainant,

v.

PERDUE FARMS, INC.,

Respondent.

ARB Case No.: 2017-0017
ALJ Case No.: 2016-FDA-00003

AMICUS UNITED STATES FOOD AND DRUG ADMINISTRATION'S BRIEF OF POINTS AND AUTHORITIES

FOR FURTHER CONSIDERATION OF FINAL DECISION AND ORDER DATED MARCH 5, 2019

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INTEREST OF AMICUS FDA

The United States Food and Drug Administration (FDA) is the federal agency entrusted to "protect the public health by ensuring that . . . foods are safe." 21 U.S.C. § 393(b)(2)(A). As part of its broader regulatory and oversight mission, FDA administers and enforces provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA).

FDA's interest in this case is in the definition of "food" under the FFDCA; specifically, FDA is interested in ensuring that live poultry intended for use as food is "food" within the meaning of the FFDCA. As part of its regulatory authority, FDA has long regulated live animals intended for use as food *as* food under the FFDCA. *See* 21 U.S.C. § 321(f). For example, to protect the public from potential harm associated with unsafe drug residues, FDA issues warning letters and seeks injunctions when edible tissues of food-producing animals contain unsafe levels of animal drug residues, causing that food to be adulterated. *See* 21 U.S.C. § 342(a)(2)(C)(ii). Thus, FDA's ability to protect the food supply depends on the scope of the FFDCA extending to live animals intended for use as food.

The instant case implicates FFDCA's definition of food as part of an employee protection case initiated under a provision added to the FFDCA by the FDA Food Safety Modernization Act. Pub. L. No. 111-353, § 402, 124 Stat. 3885, 3968 (2011) (codified at 21 U.S.C. § 399d). This provision covers employees of

entities "engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food." 21 U.S.C. § 399d(a). Although FDA does not enforce the employee protection provision, it is part of the FFDCA and, thus, involves the question of whether live poultry on a farm falls under the FFDCA's food definition and may be regulated as such under the FFDCA. FDA respectfully submits this amicus brief to aid the Department of Labor Administrative Review Board's application of the law insofar as it involves the definition of food under the FFDCA and to promote a consistent application of the statutory definition that is in harmony with FDA's mission to ensure that food is safe.[1]

As an agency of the United States, FDA files this amicus brief pursuant to FED. R. APP. P. 29(a)(2) and the Administrative Review Board's February 12, 2020, "Order Inviting Supplemental Briefing."

[1] FDA takes no position on the final outcome of this matter or other issues relevant to its resolution, including, but not limited to, whether Mr. Watts was an employee of Perdue Farms or whether Mr. Watts reasonably believed he was alleging a violation of the FFDCA. *See* 21 U.S.C. § 399d(a).

INTRODUCTION

This dispute involves the whistleblower provision of the FDA Food Safety Modernization Act (FSMA), which is incorporated into the Federal Food, Drug, and Cosmetic Act (FFDCA) at 21 U.S.C. § 399d. Respondent Perdue Farms, Inc. (Perdue) and its amici contend that Perdue is not subject to this provision because the Poultry Products Inspection Act (PPIA), not the FFDCA, applies. Specifically, they contend that live animals intended for use as food are regulated under the PPIA, rather than as food under the FFDCA. Within arguments made previously before this Board, Perdue incorrectly implied that FDA agreed that live food animals were exempt from regulation under the FFDCA and also included incomplete quotations of the PPIA, omitting critical language dispositive of this matter. Perdue's reading is inconsistent with the statutory history of the FFDCA and its relation to the PPIA. Its interpretation runs afoul of the statutory language, legislative history, and decades of practice and should thus be rejected.

Petitioner Craig Watts initiated this matter before the Occupational Safety and Health Administration alleging that Perdue violated the employee protection provisions enacted under FSMA and incorporated into the FFDCA. In his complaint, Mr. Watts stated that he raised chickens for Perdue pursuant to a contract. Notice of Whistleblower Complaint (Feb. 23, 2015) at 2. Mr. Watts claims that he uses "feed, medications, and other supplies provided by Respondent

[Perdue]." *Id.* Perdue acknowledged that "Perdue will consign chicks and provide feed, fuel, medications, vaccinations, and other supplies to Watts." Respondent Perdue Farms, Inc.'s Motion to Dismiss for Lack of Subject Matter Jurisdiction (May 31, 2016) at 5. Mr. Watts alleged that he was an employee of Perdue. Notice of Whistleblower Complaint (Feb. 23, 2015) at 2. Mr. Watts further alleged that Perdue violated the whistleblower protection provisions by taking adverse actions against him in response to his efforts to oppose the use of the phrase "Humanely Raised" on labeling for poultry sold by Perdue. Notice of Whistleblower Complaint (Feb. 23, 2015) at 7-12.

Because the whistleblower provision at issue in this case is incorporated into the FFDCA, the parties' arguments before the Board included analysis of whether the live poultry raised by Mr. Watts and intended for use as food was "food" under the FFDCA. Resolution of this question is significant to the instant dispute because it is relevant to determining whether Perdue was subject to the requirements of the whistleblower provision at all. The question is also important to FDA, as the federal agency primarily responsible for implementing the FFDCA, because it could affect the scope of the agency's jurisdiction and thus its ability to promote a safe food supply.

Arguments from Perdue and amici that suggest that on-farm live poultry is not food for purposes of applying the FFDCA whistleblower provision ignore that

a matter must fall within the "application or extension" of the PPIA to be exempt from the FFDCA. 21 U.S.C. § 467f(a). The FFDCA's jurisdiction extends to live poultry intended for use as food because the PPIA inspection provisions do not extend USDA jurisdiction to live poultry prior to its arrival at an "official establishment" (*i.e.*, a slaughter and processing facility). Thus, the exemption to the FFDCA's requirements contained in the PPIA, likewise, does not extend to live poultry on farms.

SUMMARY OF THE ARGUMENT

Although the relationship between the jurisdictions of FDA and the United States Department of Agriculture (USDA) is complex, the law is clear that live animals intended for use as food, including poultry, fall within the FFDCA definition of "food" and that FDA has authority under the FFDCA to regulate live animals on the farm when those animals are intended for use as food.

FDA has consistently regulated as food live animals intended for use as food. This is based on the plain language of the statute, judicial opinions, and legislative history. FDA's interpretation has been conveyed in numerous FDA regulations, guidance documents, and enforcement and advisory actions, as well as in joint documents authored with USDA. FDA's authority to regulate live animals, including poultry, as food is essential to the agency's ability to fulfill its mission to promote United States food safety and to the joint efforts of FDA and USDA to

ensure seamless protection of meat and poultry from farm to table. This authority is important to the public health because there are significant food safety provisions related to drug residue regulation in edible animal tissue found under the FFDCA that do not exist under other federal statutes.

The Poultry Products Inspection Act (PPIA) exempts live poultry from the FFDCA *only to the extent that the PPIA applies*. The PPIA applies to poultry and poultry products in an "official establishment" that is regulated by USDA. "Official establishment" is defined in the PPIA as "any establishment as determined by the Secretary at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained under the authority of [the PPIA]." 21 U.S.C. § 453(p). It does not apply to live poultry prior to its arrival at such an "official establishment," and it does not exclude poultry from the FFDCA's definition of food. For these reasons, live poultry on the farm is properly regulated by FDA as food under the FFDCA.

Further, the animal feed that Perdue provided to Petitioner Watts is also food within the meaning of the FFDCA and, thus, may provide an additional basis for determining whether Perdue is a covered entity under the whistleblower provision.

ARGUMENT

Under the FFDCA, live animals intended for use as food are food. Although the United States Department of Agriculture (USDA) has exclusive jurisdiction

over certain parts of the production process of poultry and poultry products under the PPIA, that jurisdiction does not begin until the animals arrive at an "official establishment" (*i.e.*, a slaughter and processing facility). Thus, live food-producing animals on the farm are regulated as food under the FFDCA. Moreover, there is no question that animal feed is "food" within the meaning of the FFDCA.

I. Live Animals Intended for Use as Food Are Regulated under the FFDCA

Pursuant to the plain language of statutory text and its broad mission to ensure that foods are safe, FDA has long regulated live food-producing animals, including live poultry, as food, and courts and legal authorities have routinely upheld FDA's authority in this area.

Under the FFDCA, food is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C. § 321(f). FDA has consistently interpreted this broad definition to include live animals intended for use as food and has used this authority to ensure that drug administration to food-producing animals does not endanger human health. FDA's interpretation has been broadly disseminated

through regulation,[2] in FDA publications,[3] and in enforcement and advisory actions.[4]

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[2] *See* 21 C.F.R. §§ 1.377 ("Food has the meaning given in section 201(f) of the act (21 U.S.C. 321(f)). Examples of food include . . . live food animals."); 1.227 ("Examples of food include . . . live food animals"), 1.276(b)(5)(ii) ("Examples of food include . . . live food animals."), 1.328 ("Examples of food include . . . live food animals.").

[3] *See*, *e.g.*, FDA, Investigations Operations Manual (2020), at 2-16, § 2.7.1.3.2, https://www.fda.gov/media/113432/download ("Examples of food include . . . live food animals."); FDA, Animal Products FDA Regulates (Nov. 2017), https://www.fda.gov/animal-veterinary/resources-you/animal-products-fda-regulates ("For regulatory purposes, live animals are considered unprocessed food."); Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 80 Fed. Reg. 74,226, 74,257 (Nov. 27, 2015) ("[L]ive animals, such as poultry and cattle, are not subject to the USDA requirements under the [Federal Meat Inspection Act] or PPIA at the time of importation. Indeed, FDA has exercised authority and responsibility over the importation of live food animals."); FDA, Center for Veterinary Medicine, Compliance Program Guidance Manual 7371.006, Illegal Residues In Meat, Poultry, Seafood, and Other Animal Derived Foods (Aug. 2005), at 5, https://www.fda.gov/media/74810/download ("[L]ive animals raised for food are 'food' under the Act."); FDA, Center for Veterinary Medicine, Compliance Policy Guide 615.200, Proper Drug Use and Residue Avoidance by Non-Veterinarians (July 1993), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-615200-proper-drug-use-and-residue-avoidance-non-veterinarians ("FDA regards live animals raised for food as 'food' under the Act.").

[4] *See United States v. Scenic View Dairy, L.L.C*, 2011 WL 3879490, at *2 n.2 (W.D. Mich. Sept. 1, 2011) ("Animals intended for slaughter have been held to constitute food within the meaning of the [Federal Food, Drug, and Cosmetic] Act"); *United States v. Rhody Dairy, L.L.C.*, 812 F. Supp. 2d 1239, 1242 (W.D. Wash. 2011) (granting injunction against dairy farm that sold cattle for food after noting that a required element of the statutory violation is that "the product at issue is food"); Warning Letter from Cheryl A. Bigham, Program Division Director, FDA Office of Human and Animal Food, to Kevin Klug (Aug. 28, 2019), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/kevin-klug-588725-08282019 (advising dairy operation that cow intended for slaughter was adulterated because of unsafe animal

Recognizing that the purpose of the FFDCA is to protect food safety, courts have upheld FDA's interpretation to encompass live animals intended for use as food. *United States v. Tuente Livestock*, 888 F. Supp. 1416, 1426 (S.D. Ohio 1995) (holding that "Hogs are food"); *United States v. Tomahara Enterprises Ltd.*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,217Y, 1983 WL 960719 (N.D.N.Y. 1983) (live calves intended for use as food are food) (attached as Attachment 1 to this memorandum). Although live food animals are not ready for immediate consumption, courts have explained that components of food are food under the statutory definition, even when they are still in an unprocessed or inedible form. 21 U.S.C. § 321(f)(3); *United States v. Cassaro, Inc.*, 443 F.2d 153, 155-56 (1st Cir. 1971) (flour is food under the FFDCA); *United States v. O.F. Bayer & Co.*, 188 F.2d 555, 557 (2d Cir. 1951) (green coffee beans are food).

Although USDA has exclusive jurisdiction under the PPIA over certain aspects of poultry and poultry products once they enter an "official establishment"

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drug residues); Warning Letter from Evelyn Bonnin, Program Division Director, FDA Office of Human and Animal Food, to Jelliffe Dairy Farm (Nov. 19, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jelliffe-dairy-farm-566246-11192018 (same); Warning Letter from Cheryl A. Bigham, Program Division Director, FDA Office of Human and Animal Food, to Dolezal Dairy (Aug. 29, 2018), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/dolezal-dairy-558107-08292018 (same).

that processes poultry and poultry products, *see* 21 U.S.C. § 455, USDA's jurisdiction under the PPIA does not extend to live animals on a farm.

The relationship between FDA and USDA's jurisdiction under these statutes is complex, but much of it is well established.[5] One legal textbook summarizes the relationship between FDA and USDA jurisdiction:

> FDA has exclusive regulatory jurisdiction over live animals intended to be used for food. *United States v. Tomahara Enterprises, Ltd.*, Food Drug Cosm. L. Rep. (CCH) ¶ 38,217 (N.D.N.Y. 1983). USDA has exclusive jurisdiction over the slaughter of food animals and over the subsequent processing of meat and poultry, except that USDA and FDA have joint jurisdiction over the use of food additives in meat and poultry. After processing, USDA and FDA have joint jurisdiction over the distribution of meat and poultry up to the retail establishment where it is sold. FDA has exclusive jurisdiction over retail food establishments.

PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 318 (4th ed. 2014).

Because of the interrelatedness of FDA and USDA jurisdiction, FDA works closely with USDA to ensure seamless protection of meat and poultry from farm to table. For example, in response to recent testing showing that cattle intended for use as food had been chemically contaminated by groundwater, FDA and USDA officials jointly wrote to the Secretary of the New Mexico Department of Agriculture to address the situation. In that joint letter, FDA and USDA explained

[5] This discussion of live animals and USDA authority is limited to the PPIA and the Federal Meat Inspection Act (which covers certain species, such as cattle, sheep, swine, and goats) because these statutes affect FDA's jurisdiction under the FFDCA.

that "FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over food, including milk and live animals intended for food." Letter from Frank Yiannas, Deputy Commissioner for Food Policy and Response, FDA, and Mindy Brashears, Deputy Under Secretary for Food Safety, USDA, to Jeff M. Witte, Secretary, New Mexico Department of Agriculture (Oct. 22, 2019) (attached as Attachment 2 to this memorandum).

Although FDA and USDA try to avoid duplication of effort while ensuring protection of the food supply, *see* FDA, Compliance Policy Guide Sec. 565.100, FDA Jurisdiction Over Meat and Poultry Products (Nov. 2005), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-565100-fda-jurisdiction-over-meat-and-poultry-products, there are some areas in which the FFDCA provides more specific coverage than the PPIA or Federal Meat Inspection Act. For example, the food adulteration provision in the FFDCA states that food is adulterated if it contains an unsafe new animal drug, 21 U.S.C. § 342(a)(2)(C)(ii), which would include unapproved new animal drugs and unsafe levels of animal drug residues. The adulteration definitions in the PPIA and Federal Meat Inspection Act do not contain provisions about unsafe animal drugs. *See* 21 U.S.C. §§ 453(g), 601(m). Because the FFDCA regulates live animals intended to be used for food, it authorizes injunctions of persons raising animals

for use as food to prevent unsafe animal drug residues under the FFDCA.[6] *See Scenic View Dairy*, 2011 WL 3879490.

Thus, it is well established that live food-producing animals, including poultry, intended for use as food, are food within the meaning of the FFDCA and subject to its provisions.

II. Live Poultry Is Not Exempt from FFDCA Regulation

Perdue Farms (Perdue) argues that poultry is not subject to the whistleblower provision of the FFDCA, 21 U.S.C. § 399d, pursuant to a statutory exemption for poultry contained in the PPIA. That argument, however, misstates FDA's position and ignores a critical phrase in the exemption upon which Perdue tries to rely. More concerning for the public, by interpreting live poultry to be exempt from the jurisdiction of the FFDCA, Perdue's argument would undermine FDA's ability to protect the public from unsafe animal drugs in the food supply. Put simply, the PPIA exempts poultry and poultry products from regulation under

[6] As another example, FDA's regulation extends to the registration of certain facilities holding live animals for human or animal consumption. 21 U.S.C. § 350d(a)(1); 21 C.F.R. § 1.227 (definition of food). Although farms and facilities regulated exclusively by USDA are exempt, 21 C.F.R. § 1.226(b), (g), a stockyard or livestock market holding live food animals is not subject to sole USDA jurisdiction and therefore would generally be required to register with FDA as a food facility unless an exemption applies. *See* Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry, at 29 (Aug. 2018), https://www.fda.gov/media/85043/download.

the FFDCA (and thus the FSMA whistleblower provision) only *to the extent* that the poultry is otherwise regulated under the PPIA. Because of the PPIA's focus on the inspection of "official establishment[s] processing poultry," 21 U.S.C. § 455, the PPIA does not extend to live animals on the farm. Thus, the live poultry at issue in this matter is not exempt from the FFDCA.

A. The PPIA Does Not Extend USDA Jurisdiction to Live Animals on the Farm

Under the PPIA, poultry is exempt from the FFDCA only to the extent that the PPIA applies:

> Poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] *to the extent of the application or extension thereto of the provisions of this chapter*, except that the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to August 18, 1968.

21 U.S.C. § 467f(a) (emphasis added). This provision means that the PPIA ("this chapter") governs poultry and poultry products in the areas regulated by the PPIA,[7]

[7] The PPIA applies most directly to "official establishments" where poultry is slaughtered and processed. *Ass'n des Éleveurs de Canards et d'Oies du Quebec v. Becerra*, 870 F.3d 1140, 1153 (9th Cir. 2017); *see generally* 21 U.S.C. §§ 451-472. The PPIA contains provisions, "*inter alia*, authorizing the inspection of slaughterhouses and poultry-processing plants, 21 U.S.C. § 455, setting proper sanitation requirements, *id.* § 456, authorizing the Secretary of [Agriculture] to establish labeling and container standards, *id.* § 457, prohibiting the sale of adulterated, misbranded, or uninspected poultry products, *id.* § 458, establishing record-keeping requirements, *id.* § 460, and instituting storage and handling regulations, *id.* § 463." *Ass'n des Éleveurs de Canards*, 870 F.3d at 1144-45.

the most significant of which is USDA's exclusive jurisdiction over inspections in poultry processing establishments. 21 U.S.C. §§ 455, 456. If there is not a governing provision in the PPIA, however, the FFDCA continues to apply.

The PPIA provides USDA authority to inspect poultry and poultry products both ante-mortem and post-mortem, but that authority applies "in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under [the PPIA]." 21 U.S.C. § 455(a); 9 C.F.R. § 381.70(a) (providing for ante-mortem inspection of poultry "on the day of slaughter in any official establishment"); *see also* 21 U.S.C. § 455(b); *Ass'n des Éleveurs de Canards et d'Oies du Quebec v. Becerra*, 870 F.3d 1140, 1153 (9th Cir. 2017) ("The PPIA most directly regulates 'official establishments,' where the 'inspection of the slaughter of poultry, or the processing of poultry products,' occurs.").

The PPIA defines an "official establishment" as an establishment "at which inspection of the slaughter of poultry, or the processing of poultry products, is maintained under the authority of [the PPIA]." 21 U.S.C. § 453(p). It defines "processed" as "slaughtered, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed." 21 U.S.C. § 453(w). Thus, it is clear from the plain text of the PPIA that the inspections it authorizes occur – shortly before, during, or after slaughter – at the facility where poultry is slaughtered and/or

processed. The PPIA inspection provisions do not extend USDA jurisdiction to live poultry prior to its arrival at an "official establishment."

Nor do any other provisions of the PPIA extend USDA's jurisdiction to live poultry on a farm before arrival at an official establishment. The remainder of the PPIA contains provisions appurtenant to USDA's authority to inspect poultry and poultry products at official establishments. Provisions include, but are not limited to, the following: cooperation with state agencies; requirements for labeling and containers; requirements for recordkeeping; and administrative provisions for the execution and enforcement of the PPIA. *See generally* 21 U.S.C. §§ 451-472; *see also Ass'n des Éleveurs de Canards*, 870 F.3d at 1144-45. Indeed, the very text of the PPIA removes any doubt; when Congress sought to regulate activity at locations other than an "official establishment," it used the term "upon any premises" specifically authorizing action under the FFDCA.[8]

The information provided to the Board in its original consideration of this matter may have incorrectly implied that FDA agreed that live food animals were exempt from regulation under the FFDCA and also included incomplete quotations of the relevant exemption.

[8] The PPIA provision that applies to dead, dying, disabled, or diseased poultry found "upon any premises," 21 U.S.C. § 467a, is expressly applied to "any authorized representative of the Secretary of Health and Human Services for purposes of the enforcement of the [FFDCA]" for any article *outside any official establishment*. 21 U.S.C. § 467f(b).

In its briefs before the Board, Perdue cites statements from FDA reflecting that USDA "primarily" has jurisdiction over meat and poultry products. *See, e.g.*, Respondent's Brief in Opposition (March 27, 2017) at 18-19. Although it is true that USDA is the *primary* regulator for meat and poultry products, USDA's jurisdiction is by no means exclusive, and the statements Perdue cites do not suggest otherwise. Indeed, as noted above, *see supra* nn. 2-4, FDA has repeatedly and consistently asserted its jurisdiction over live food-producing animals under the FFDCA.

Further, both Respondent Perdue Farms and Amici U.S. Poultry and Egg Association and National Chicken Council omitted the most critical portion of the exemption contained in the PPIA from quotes of the PPIA in their briefs, the provision limiting the FFDCA exemption for poultry "*to the extent of the application or extension thereto of the provisions of [the PPIA]*."[9] As discussed

[9] Briefs filed by Respondent and amici selectively omitted this critical language. *See, e.g.*, Respondent's Brief in Opposition (March 27, 2017), at 2 ("First, the Poultry Products Inspection Act ('PPIA'), 21 U.S.C. § 467f(a), provides that '[p]oultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetics [sic.] Act ['FDCA')],' except that the PPIA 'shall not derogate from any authority conferred by the [FDCA] prior to August 18, 1968.'") and, at 12 ("The PPIA expressly provides that '[p]oultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act,' subject to a narrow exception that the PPIA 'shall not derogate from any authority conferred by the [FDCA] prior to August 18, 1968.'"); U.S. Poultry and Egg Association and National Chicken Council's Amicus Brief in Support of Respondent Perdue Farms, Inc. (Apr. 17, 2017) at 8 ("PPIA explicitly exempted poultry and poultry products from the authority of the Federal Food, Drug, and

above, this language makes clear that the PPIA does not exempt all poultry from the provisions of the FFDCA under all circumstances, and it is dispositive of the matter before the Board.

B. History of the Federal Meat Inspection Act and the PPIA

As explained above, live poultry remains subject to regulation under the FFDCA prior to entry into an official establishment. The history of the poultry exemption and a nearly identical exemption for meat products further solidifies this point.

Congress enacted an exemption for meat products in 1938 as part of the Federal Food, Drug, and Cosmetic Act of 1938 to address the relationship between the FFDCA and the Federal Meat Inspection Act. The Federal Meat Inspection Act requires that meat and meat products are slaughtered and processed under strictly regulated conditions, and this exemption ensures that the Federal Meat Inspection Act is the governing law for slaughter and processing.

> Meats and meat food products shall be exempt from the provisions of this Act [the FFDCA] *to the extent of the application or the extension thereto of the Meat Inspection Act*.

Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 902(b), 52 Stat. 1040, 1059 (June 25, 1938) (citations omitted) (emphasis added) (codified at 21

Cosmetic Act ('FDCA') expect [sic.] any 'authority conferred by the [FDCA] prior to August 18, 1968.'").

U.S.C. § 392(a)). At the time this exemption was enacted, the FFDCA and the Federal Meat Inspection Act were both enforced by USDA because FDA was originally part of USDA. Thus, it is clear that the statutory language is meant to identify the governing statutory section, not the governing agency. Two years later, FDA moved to the newly created Federal Security Agency. Reorganization Plan No. IV of 1940, 5 Fed. Reg. 2421, 54 Stat. 1234 (June 29, 1940). Subsequently, the Federal Security Agency became the Department of Health, Education, and Welfare, and later the Department of Health and Human Services.

When Congress enacted the Poultry Products Inspection Act in 1957 for mandatory USDA inspections of poultry processing facilities, it included nearly identical exemption language as that in the Federal Meat Inspection Act. As with its predecessor, this provision exempted poultry and poultry products from the FFDCA to the extent they were governed by the PPIA:

> For the purpose of preventing and eliminating burdens on commerce in poultry and poultry products, the jurisdiction of the Secretary within the scope of this Act shall be exclusive and poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act, as amended, *to the extent of the application or the extension thereto of the provisions of this Act*.

Pub. L. No. 85-172, § 18, 71 Stat. 441, 448 (1957) (emphasis added). The House Report explained that this provision "gives the Secretary of Agriculture exclusive jurisdiction over poultry and poultry products within the scope of this bill and

provides the same exemption for poultry and poultry products from the Federal Food, Drug, and Cosmetic Act as presently applies to red meats." H.R. Rep. No. 85-465, at 6-7 (1957). The Senate Report agreed that this language "provides the same exemption for poultry and poultry products from the Federal Food, Drug, and Cosmetic Act as presently applies to red meats." S. Rep. No. 85-195, at 6 (1957). As a USDA official explained, the exemption prevented any gaps in the application of the two laws while avoiding duplication of effort:

> The purpose of this [exemption provision] is to avoid overlapping jurisdiction of the two acts and therefore prevent needless duplication of effort. At the same time the provisions of the Food, Drug, and Cosmetic Act would apply to any circumstances beyond the application of this Poultry Inspection Act, and also prevent any gaps in the application of these two laws. Under this provision we feel that the same relationships would exist between the poultry inspection program and the Food and Drug Administration as now exist between the red meat inspection program and the Food and Drug Administration. The Department [of Agriculture] believes that this subsection (a) is appropriate in that it assures complete coverage without duplication.

Hearings before the Committee on Agriculture and Forestry, 85th Cong., on S. 313, S. 645, and S. 1128, at 106 (Comm. Print 1957) (statement of Hermon I. Miller, Director, Poultry Division, Agricultural Marketing Service, USDA).

Thus, as the scope of the meat exemption depends on the scope of the Federal Meat Inspection Act, so too is the scope of the poultry exemption defined by the scope of the PPIA. Because the PPIA applies most directly to "official

establishments," live poultry is not exempt from the FFDCA. Indeed, the House Report accompanying the 1957 passage of the PPIA recognizes this explicitly, explaining: "The bill does not regulate in any manner the handling, shipment, or sale of live poultry." H.R. Rep. No. 85-465, at 1 (1957).[10] Because on-farm live poultry were not regulated under the PPIA, they were not covered by the exemption provision.

A decade later, Congress amended the exemptions in the PPIA and the Federal Meat Inspection Act when it made changes that would have otherwise limited the coverage of the FFDCA over meat and poultry. The Wholesome Meat Act of 1967 and Wholesome Poultry Products Act of 1968 gave USDA authority over adulterated and misbranded meat and poultry products after those products left the USDA-regulated processing facility. Pub. L. No. 90-201, § 7, 81 Stat. 584, 589 (1967) (meat); Pub. L. No. 90-492, § 9, 82 Stat. 791, 800 (1968) (poultry).

[10] At the time, USDA already had separate legal authority to inspect live poultry for "contagious, infectious, and communicable diseases," 7 U.S.C. § 391, and to prohibit the interstate sale of diseased poultry. *See* Act of February 7, 1928, c. 30, 45 Stat. 59. USDA began to offer a voluntary inspection and grading service to poultry processors through its Federal Poultry Inspection Service in 1926. National Research Council Committee on Public Health Risk Assessment of Poultry Inspection Programs, *Poultry Inspection in the United States: History and Current Procedures*, in POULTRY INSPECTION: THE BASIS FOR A RISK-ASSESSMENT APPROACH (1987), https://www.ncbi.nlm.nih.gov/books/NBK218008/. USDA also had authority over live poultry under laws such as the Agricultural Marketing Act and the Packers and Stockyards Act. USDA authority under these laws, however, is irrelevant to determining the scope of the PPIA exemption.

This new authority would have superseded the FFDCA to the extent the PPIA or Federal Meat Inspection Act applied. To avoid that result, Congress specified that the Wholesome Poultry Products Act did not derogate from the FFDCA's preexisting coverage of poultry or poultry products:

> Poultry and poultry products shall be exempt from the provisions of the Federal Food, Drug, and Cosmetic Act to the extent of the application or extension thereto of the provisions of this Act, except that the provisions of this Act shall not derogate from any authority conferred by the Federal Food, Drug, and Cosmetic Act prior to enactment of the Wholesome Poultry Products Act.

Pub. L. No. 90-492, § 17, 82 Stat. 791, 807 (1968) (codified at 21 U.S.C. § 467f(a)). The Federal Meat Inspection Act was similarly amended to maintain preexisting FFDCA coverage over meat. Pub. L. No. 90-201, § 16, 81 Stat. 584, 600 (1967) (codified at 21 U.S.C. § 679(a)).

These amended exemptions mean that both USDA and FDA have jurisdiction over adulterated and misbranded meat and poultry once they leave USDA-regulated facilities. The Senate Report for the Wholesome Meat Act explained that the Secretaries "would thus have concurrent jurisdiction under the Meat Inspection Act and the Federal Food, Drug, and Cosmetic Act over meats and meat food products becoming adulterated or misbranded after inspection." S. Rep. No. 90-799, at 14 (1967). Dual jurisdiction exists after inspection because both the FFDCA and the Federal Meat Inspection Act (as amended by the Wholesome Meat

Act) prohibit the distribution in interstate commerce of misbranded or adulterated meat. The Federal Meat Inspection Act gives USDA exclusive jurisdiction within the processing facility, but not over live food animals on the farm. *See generally* 21 U.S.C. §§ 601-626. The House Report for the Wholesome Meat Act added that Congress intended for FDA and USDA to exercise this patchwork of jurisdiction to avoid conflicts:

> [T]he committee intends that the authority of the Secretary of Agriculture and the authority of the Secretary of Health, Education, and Welfare not be exercised in a manner that will cause any overlapping or conflicting requirements. It is the committee's intent that both Secretaries shall, to the maximum extent feasible in the administration of this act and the Federal Food, Drug, and Cosmetic Act, exercise their respective authorities in connection with matters subject to concurrent jurisdiction under these acts in such manner as to avoid any unnecessary duplication of effort.

H.R. Rep. No. 90-653, at 11 (1967).

For the Wholesome Poultry Products Act, the Senate Report and House Report explained that the provision in the PPIA parallels "the [Federal Meat Inspection Act] with respect to meat and meat food products." H.R. Rep. No. 90-1333, at 28 (1968); S. Rep. No. 90-1449, at 23 (1968). Because FDA had jurisdiction over adulterated and misbranded meat and poultry before passage of the Wholesome Meat and Wholesome Poultry Products Acts, *see United States v. Kocmond*, 200 F.2d 370, 373 (7th Cir. 1952) (upholding misbranding conviction under the FFDCA for horse meat that was labeled only as "chucks" and "chunks");

United States v. Diamond State Poultry Co., 125 F. Supp. 617, 617 (D. Del. 1954) (imposing criminal conviction for selling adulterated poultry in interstate commerce under the FFDCA), it continues to have jurisdiction over adulterated and misbranded meat and poultry today.

Arguments from Perdue and amici that suggest that on-farm live poultry is not food for purposes of applying the FFDCA whistleblower provision ignore that a matter must fall within the "application or extension" of the PPIA to be exempt from the FFDCA. Because the PPIA does not extend to live poultry prior to arrival at an "official establishment," the PPIA does not apply to live animals on the farm, and therefore does not exempt them from regulation under the FFDCA. Furthermore, based on judicially recognized precedent, live food animals are food. For these reasons, FDA respectfully requests that the parties and the Board reconsider the basis for the Board's March 5, 2019, Final Decision and Order.

III. Animal Food is Food

In addition to the fact that live poultry on the farm is food, FDA notes that there is another connection to food that may be relevant to the Board's evaluation of whether Perdue is a covered entity under the FFDCA whistleblower provision.

The whistleblower provision covers entities "engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food," 21 U.S.C. § 399d(a); *see* 29 C.F.R. § 1987.101(d) ("*Covered entity*

means an entity engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food."). The FFDCA defines food to include "articles used for food or drink for man or other animals." 21 U.S.C. § 321(f)(1); *see* 21 C.F.R. § 507.3 ("*Animal food* means food for animals other than man and includes pet food, animal feed, and raw materials and ingredients."); *see also* Department of Labor, Investigator's Desk Aid to the FDA Food Safety Modernization Act (FSMA) Whistleblower Protection Provision, at 3 (Aug. 2018), https://www.osha.gov/sites/default/files/FSMADeskAid.pdf (explaining that the FFDCA "definition of 'food' includes . . . animal feed.").

In his complaint, Mr. Watts states that he "feeds, waters, and cares for those flocks using feed, medications, and other supplies provided by Respondent [Perdue]." Notice of Whistleblower Complaint (Feb. 23, 2015), at 2. Perdue Farms acknowledges that "Perdue will consign chicks and provide feed, fuel, medications, vaccinations, and other supplies to Watts." Respondent Perdue Farms, Inc.'s Motion to Dismiss for Lack of Subject Matter Jurisdiction (May 31, 2016), at 5. Under the Poultry Producer Agreement, Mr. Watts was required to use only the animal food provided by Perdue. Exhibit 1 to Perdue's April 27, 2015 Letter to W. Peterson, OSHA Regional Investigator ("PRODUCER AGREES… [t]o use only the feed, fuel, medications, vaccinations, and other supplies, which

PERDUE has provided, or has arranged to be provided, to PRODUCER for the raising of the chicks consigned.").

Thus, independent of any discussion of live poultry, the fact that Perdue distributed food in the form of animal feed to Mr. Watts is relevant to the Board's evaluation as to whether Perdue is a covered entity under 21 U.S.C. § 399d, as an entity engaged in the distribution of food (in this case, animal feed).[11]

IV. Conclusion

For the reasons discussed above, FDA respectfully requests that the Board reconsider and overturn its holding that it lacked subject matter jurisdiction over the instant case on the basis that Perdue was not engaged in the manufacture, processing, packing, transporting, distribution, reception, holding, or importation of "food" within the meaning of the FFDCA.

Respectfully submitted,

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ANNAMARIE KEMPIC

[11] Although live poultry and animal feed are food under the FFDCA, FDA takes no position as to whether Mr. Watts was an employee of Perdue or whether he reasonably believed that the information he provided related to a violation of the FFDCA and its implementing orders, rules, regulations, standards, or bans. 21 U.S.C. § 399d(a)(1).

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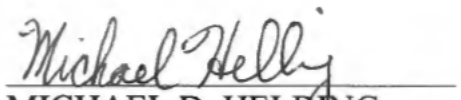
By: 

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Dated: March 11, 2020

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Attorney for United States Food and Drug Administration

Dated: March 11, 2020

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that service of the foregoing Amicus United States Food and Drug Administration's Brief of Points and Authorities has been served on the following via United States Mail, postage prepaid, on this 11th day of March, 2020:

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Dated: March 11, 2020

ATTACHMENT 1

Food Drug Cosm. L. Rep. P 38217Y (C.C.H.), 1983 WL 960719

Food Drug Cosmetic Law Reporter

U.S. District Court, N.D. New York | March 29, 1983
No. 83-CV-233

Neal P. McCurn

¶ 38,217Y UNITED STATES OF AMERICA V. TOMAHARA ENTERPRISES, LTD. D/B/A TOMAHARA FARMS, AND EDWARD CONHAIM AND GUSTAF VANGENECHTEN, INDIVIDUALS

Adulteration —— Regulatory Scoped —— Definition of Food —— Live Calves

The edible tissues of live veal calves that were allegedly adulterated because they contained diethylstilbestrol (DES) constituted 'food' as defined by the Federal Food, Drug, and Cosmetic Act and were, therefore, subject to the adulteration provisions of the Act. The defendant veal farm had argued that the calves were not food while they were alive because they were capable of being eaten only after they were slaughtered. However, food need not be in its final form to constitute 'food' under the FDC Act. The fact that the calves were not capable of being eaten at the time of alleged adulteration was immaterial because they were capable of being eaten after slaughter and were raised solely for that purpose. The main concern was whether the veal calves had been given an unapproved new animal drug. Because it was within the expertise of the Food and Drug Administration to approve or disapprove the use of new animal drugs, it was a logical extension to find that the animals injected with the drug were under the jurisdiction of the FDA. The government's motion for a preliminary injunction was granted.

Adulteration —— Exemption for Meat and Meat Food Products —— Live Calves

The edible tissues of live veal calves that were allegedly adulterated because they contained diethylstilbestrol were not 'meat' or 'meat food products' as defined by the Meat Inspection Act and were, therefore, not exempt from the application of the Federal Food, Drug, and Cosmetic Act. The terms 'meat' and 'meat food product' were intended to include only the edible tissues of animals after slaughter. This interpretation was supported by the limited nature of the MI Act definition and by the fact that live animals were included within the definition of 'livestock' in certain federal regulations, but were not mentioned in the FDC Act exemptions. Even if the MI Act did apply to live animals and would provide a basis for governmental action, it did not preclude the government from proceeding under the FDC Act. The MI Act specifically provides that its provisions shall not derogate any authority conferred by the FDC Act, and the legislative history demonstrates that there would be concurrent jurisdiction under the MI Act and the FDC Act over meats and meat food products becoming adulterated or misbranded after inspection.

Adulteration —— Unsafe New Animal Drug —— Preliminary Injunction —— Burden of Proof

In an action seeking a preliminary injunction against a veal farm because of its alleged use of diethylstilbestrol (DES) in veal calves, the government established a probable likelihood that the calves were adulterated within the meaning of the FDC Act. DES was a new animal drug for which there was no approved application for use in veal calves and whose presence in food was unsafe at any detectable level. Tests of the liver and kidneys of some of the animals showed detectable levels of DES, as

did subsequent fecal samples from the animals. FDA scientists were also of the opinion that the edible tissues of the calves on the farm contained DES. The defendant had argued that the test results could be interpreted as showing only that the manure of the animals and not the calves themselves contained DES. On the application for preliminary relief, however, the government did not have to prove contamination, but only needed to show a probable likelihood that it could be proved at trial.

Enforcement —— Injunction —— Irreparable Harm

In an action seeking a preliminary injunction against a veal farm because of its alleged use of diethylstilbestrol in calves, the government did not have to make a showing of irreparable harm because it was a proceeding under the Federal Food, Drug, and Cosmetic Act. The passage of the Act itself was an implied finding that violations would harm the public and, if necessary, should be restrained. Aside from such an implied finding, the government demonstrated that the slaughtered calves would cause the public irreparable harm if used for food.

Enforcement —— Interstate Commerce Preliminary Injunction —— Burden of Proof

In an action seeking a preliminary injunction against a veal farm because of its alleged use of diethylstilbestrol in calves, the government established a reasonable likelihood that it could prove at trial that the veal calves were in interstate commerce. The defendant stated that it often used buyers who were outside the state to arrange for the purchase of the calves, and the defendant did not have the purchase orders for the calves currently being held on the farm. In addition, the defendant offered the calves for slaughter to slaughterhouses that were involved in interstate commerce. In the action for preliminary relief, the government did not have to prove to a certainty that the calves were not purchased within the state.

Veterinary drugs —— Unapproved New Drug —— Interstate Commerce

In a preliminary injunction action against a veal farm for its alleged use of diethylstilbestrol (DES) in veal calves, the government failed to establish that the drug had been in interstate commerce. The government had argued that, because there were no licensed manufacturers of the drug in the state, the defendant must have obtained the drug in interstate commerce. However, because there may not be any facility in the country licensed to manufacture the drug, it could not be said that the drug must have passed through interstate commerce. The government made no showing of where the drug was manufactured. Although injunctive relief could not be based on the contention that DES was an adulterated drug in interstate commerce, the government‘s motion for preliminary relief was granted on other grounds.

Attorneys for defendants: Richard G. Compson and Salvador J. Capecelatro, Utica, New York.
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UNITED STATES OF AMERICA v. TOMAHARA ENTERPRISES, LTD. d/b/a TOMAHARA FARMS, AND EDWARD CONHAIM AND GUSTAF VANGENECHTEN, INDIVIDUALS

UNITED STATES OF AMERICA v. TOMAHARA ENTERPRISES, LTD. d/b/a TOMAHARA FARMS, AND EDWARD CONHAIM AND GUSTAF VANGENECHTEN, INDIVIDUALS

In the U.S. District Court, N.D. New York. No. 83-CV-233. Memorandum Decision and Order dated March 29, 1983.

Attorneys for defendants: Richard G. Compson and Salvador J. Capecelatro, Utica, New York.

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Majority Opinion

MEMORANDUM-DECISION AND ORDER

Background

Edward M. Conan:[1] Plaintiff filed its complaint for injunction on March 2, 1983 and that day sought a temporary restraining order enjoining the defendants and their agents from using DES, from offering for slaughter as food any veal calves which had been administered DES, and from offering for slaughter as food any animals on Tomahara Farm. That motion was heard by District Judge Neal P. McCurn and an Order was granted. Judge McCurn thereafter conducted several conferences with the parties and signed an Order extending the TRO for an additional 10-day period. When it became evident that an evidentiary hearing would be necessary to the resolution of the case, the parties consented to the referral of this case to the undersigned. The evidentiary hearing commenced on March 16, 1983, and concluded on March 18, 1983. This opinion shall constitute the Court's finding of facts and conclusions of law. Fed. R. Civ. P. 52(a).

Facts

The parties in the action are the United States, in the persona of the Food and Drug Administration [FDA], Tomahara Enterprises, d/b/a Tomahara Farms, a New York corporation doing business primarily as a veal farm in New Hartford, New York, and Edward Conhaim, the President and sole stock holder of Tomahara Enterprises, Ltd.[2] [Hereinafter, the defendants will be referred to in the singular].

Tomahara Enterprises, Ltd., purchased what is now called Tomahara Farms in 1978. The defendant's veal operation is housed on that farm in a single barn. The barn is divided into four holding rooms, in addition to a feed storage room. Each holding room is equipped with approximately 100 pens, each designed to hold one veal calf. The pens are approximately the size of three orange crates, have a slatted bottom, and are raised eighteen inches above a concrete floor.

The defendant testified that he engages buyers to purchase veal calves for the farm. After purchase, the calves are placed in their pens, restrained by neck chains, and are there held until they are ready for slaughter, some twelve to sixteen weeks later. The defendant offers the calves to several slaughterhouses in New York, including Utica Veal in Utica, New York.

Sometime in November, 1982, defendant met an individual named Gus Vangenechten and offered him a position as barn manager. The government avers that Mr. Vangenechten was identified by U. S. Customs as a party violating 10 U. S. C. § 1497 on August 30, 1982, by importing into the United States an undeclared, unidentified substance, later determined to be DES dipropionate. The government further avers that he has been identified as a person supplying a veal producer with DES, and giving the producer instructions as to its oral administration to veal calves. See Aff. of E. Pitt. Smith, Pl. Ex. 3.

Although the specifics of Mr. Vangenechten's position at Tomahara are not clear, it appears that he was working on a salary plus commission basis. Mr. Vangenechten took up residence on the farm, received free room and board, and was given a weekly allowance "to live on". Defendant testified that he told Mr. Vangenechten that if the farm turned an increased profit due to a change in market conditions, he would be compensated accordingly, by a percentage of the profits. Defendant described this as a loose arrangement.

Mr. Vangenechten's duties included "doing everything" with the veal calves, including the administration of medications. He was hired to follow the defendant's program for raising veal calves. Defendant described his program as follows: all calves begin the program by receiving mastitis treatments in their ears, iodine in their navels, and vaccinations. They then receive neomyacin for two days, and sometimes mucci, depending on the time of year. All calves receive electrolytes.

Defendant administers vitamins to the calves on an "as needed" basis, normally by means of an injection. He varied this aspect of the program during Mr. Vangenechten's tenure to accommodate his preference for oral administration. Defendant testified that he has never administered any growth promoters to his calves. However, when Mr. Vangenechten worked on the farm, defendant did not "step foot" into the barn, giving Mr. Vangenechten total responsibility for the animals' daily care.

[*Inspections and Tests*]
On January 7, 1983, defendant offered 45 veal calves for slaughter at Utica Veal. The USDA randomly sampled liver and kidney tissues from five of the calves. Tests performed on these samples demonstrated the presence of Diethylstilbestrol [DES.] in each sample.

On January 10, 1983, defendant offered 47 veal calves to Utica Veal for slaughter. Again, five liver and kidney samples were taken. Once again, detectable levels of DES were found in the samples. Sometime after this second sale, defendant dismissed Mr. Vangenechten.

On January 13, 1983, FDA investigators David Kiessling and James Evans conducted an inspection of the veal calf barn on Tomahara Farms. At that time, the veal calf operation consisted of: 91 veal calves, approximately one week old; 100 veal calves, approximately four weeks old; and 100 veal calves, approximately eight weeks old. The investigators first inventoried the drug cabinet located in the barn and took a sample of a white substance later revealed to be penicillin. The investigators next entered room number 3, where they found a newly arrived lot of one week old calves. The investigators took fecal samples from these calves. Due to the fact that the calves had only been in that room for less than one day, the investigators were only able to collect two samples. These were obtained by scraping the bottom of the animals' pens with a sterile scoop. The samples were then placed into a sterile specimen cup.

The investigators then proceeded to room number 4, where 100 calves, aged approximately 8 weeks were located. According to the testimony of Supervising Investigator Kiessling, the defendant informed the investigators that the animals were too "spooky" for the investigators to collect the samples in the same manner as was done in the first room. Defendant then offered the investigators a shovel which was washed in hot water then used to remove the samples from the concrete floor beneath the pens. Samples were collected in a like manner from room 2.

The investigators next took samples of the feed then in use in the barn. During their investigation, the investigators found a pellet gun that was of the type formerly used to implant DES pellets in the ears of cattle. The investigators conducted an exit interview with the defendant at which they gave him receipts for the samples taken and questioned him about DES. Defendant stated that he did not know anything about DES and did not know what the gun was used for. He guessed that the gun had been left behind by the previous owner of the farm.

After leaving the farm, the investigators returned to the FDA laboratory in Syracuse, New York. Investigator Evans then proceeded to label and bag the samples collected. The samples were then placed in one large bag and sealed. That seal was broken by Mr Evans on January 14, 1983 and again on January 17, 1983. The bag was resealed each time the seal was broken. On January 17, 1983 the samples were delivered to Emery Air Freight for transport to the FDA laboratory in Denver, Colorado.

Upon arrival at the Denver facility, the samples came into the possession of Susan Torda, a chemist with the veterinarian section of the FDA. She analyzed the samples taken from defendant's barn for residues of DES by means of Gas Liquid Chromatography.

Gas Liquid Chromatography is a method whereby a drug is separated using an instrument called the GLC. That instrument is divided into five parts: inert gas; a vapor chamber; a column upon which the sample is separated from any interfering components; a detector which detects the drug; and a recorder which records what the detector has seen. The results of Ms. Torda's analysis of the samples taken from defendant's farm were that the fecal material contained detectable levels of DES, some at 10 parts per billion, some at 14 parts per billian [ppb]. No detectable levels of DES were found in the feed samples analyzed.

At the conclusion of Ms. Torda's analysis, she delivered the assay portion of the samples to Mr. William Morris, a research chemist with the FDA and a National Expert in Mass Spectroscopy. He used an instrument called the Mass Spec to do confirmatory tests on the samples tested by Ms. Torda.

The Mass Spec is a method of introducing a sample into a core and converting it into a vapor. Helium then pushes the vapor onto the head of a column. As the column increases slowly in temperature, the compounds come off the column and are then analyzed by size, weight and chemical structure. The Mass Spec is able to produce a "finger print" of the compounds it analyzes. The tests run by Mr. Morris on the fecal samples from defendant's farm confirmed the presence of DES.

Some time after receiving the test results, the FDA filed suit in this Court seeking equitable relief. It is the position of the government that the veal calves on defendant's farm have been administered DES, and are therefore adulterated food, unfit for human consumption. See 21 U. S. C. §§ 310-

Discussion

The Applicable Statute

Plaintiff brings this action under the Federal Food, Drug and Cosmetic Act. 21 U. S. C. §§ 310-392. Plaintiff alleges that the defendant has violated 21 U. S. C. § 351(a)(5) in that he has allegedly caused the adulteration of a drug, DES, and 21 U. S. C. § 342(a)(2)(D), in that he has allegedly caused the adulteration of the edible tissues of veal calves, both prohibited acts within the meaning of 21 U. S. C. § 331 (a). Defendant argues that the alleged adulteration of the edible tissues of these veal calves is not governed by the Food, Drug and Cosmetic Act [FDCA], but rather by the Meat Inspection Act [MIA], 21 U. S. C. §§ 601-695. *See* 21 U. S. C. § 392(a). The determination of which Act applies is critical, because the definition of adulteration is different under each statute. There is no question that the alleged adulteration of the drug, DES, is governed by the FDCA. Before determining whether the alleged adulteration of the edible tissues of the veal calves is exempted from regulation by the FDCA, the Court must first determine whether the calves are regulated by the FDCA in the first instance.

Plaintiff has accused the defendant of violating 21 U. S. C. § 331(a) which prohibits the "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded" Defendant first contends that this section is inapplicable because the live veal calves are not food within the meaning of the FDCA.

[*Definition of "Food"*]

The FDCA defines food as "(1) articles used for food or drink for man or other animals, … (3) articles used for components of any such article." 21 U. S. C. § 321(f). It is the government's contention that the edible tissues of these calves are "food" because the animals are being raised for the sole purpose of providing food. The defendant, on the other hand, argues that the veal calves are not food while alive; that they are capable of being eaten only after they are slaughtered.

The government has cited no cases, nor has the Court found any, which hold that live animals raised for the purpose of providing food after slaughter are food within the meaning of section 321(f). It is clear, however, that food need not be in its final form to constitute "food" under the definition of the FDCA. See, e. g., *United States v. H. B. Gregory Co.*, 502 F. 2d 700 (7th Cir. 1974) (corn meal, poppy seeds, caraway seeds and corn grits are food); *United States v. Cassaro*, 443 F. 2d 153 (1st Cir. 1971) (flour is food); *Otis McAllister Co. v. United States*, 194 F. 2d 386 (5th Cir. 1952) (green coffee is food); *United States v. Article of Food*, 414 F. Supp. 793 (E. D. Mo. 1976) (orotic acid is food). When faced with the question whether green coffee beans are food, the Second Circuit stated: "it is common knowledge, of which a court may take judicial notice, that the drink called 'coffee' is made from roasted coffee beans. It is also common knowledge that green coffee beans are used to produce the roasted coffee beans. Hence no evidence is necessary to establish that green coffee beans are a 'food' as defined by the statute." *United States v. O. F. Bayer Co.*, 188 F. 2d 555, 557 (2d Cir. 1951).

It is the determination of this Court that judicial notice can be taken that these veal calves are "food" as defined by the statute. These calves are raised for the sole purpose of providing food. No one contends that they are being raised for any other purpose. The fact that they are not presently capable of being eaten is immaterial, as they are capable of being eaten after slaughter and are intended for that purpose.

This determination finds support in the Supreme Court case of *United States v. An Article of Drug*, 394 U. S. 784 (1969). There the Court stated that: "remedial legislation such as the Food, Drug and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public's health." 394 U. S. at 798. Giving the Act a broad construction, the Court held that an antibiotic sensitivity disc, used as a screening device to determine the proper antibiotic to be administered to a patient, was a "drug" within the meaning of the Act. *Id.;* see also O'Reilly, *Food & Drug Administration* at 9-2 (1979 ed.) (the Act is to be broadly construed "to preserve a broad range of public protection jurisdiction for the FDA").

The case presently before the Court is one which calls for the broad interpretation of the term "food". Here, the concern is whether these veal calves have been administered a "new animal drug" for which there is no approved application on file,

DES. It is the FDA which approves these applications and which has revoked the approval for the drug DES. As it is within the expertise of the FDA to approve or disapprove the use of new animal drugs, it is a logical extension to find that the animals injected with these drugs are within the jurisdiction of the FDA. See 21 U. S. C. § 360(d)(1)(h).

[*Meat Inspection Act*]
The question before the Court then becomes, whether this "food" is exempted from the application of the FDCA by the exception set forth in 21 U. S. C. § 392(a). That section provides that "[m]eats and meat food products shall be exempt from the provision of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended." Defendant contends that, pursuant to this exemption, the alleged adulteration of these calves is governed by the terms of the Meat Inspection Act [MIA], and not the FDCA. This Court does not agree.

The regulations effecting the MIA define meat as "[t]he part of the muscle of any cattle … which is skeletal … with or without the accompanying and overlying fat, and the portions of bone, skin, sinew, nerve and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing." 9 C. F. R. § 301.2tt. The MIA defines meat food product as "any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle…." 21 U. S. C. § 610(j).

It is the determination of this Court that the terms meat and meat food product are intended to include only the edible tissues of animals after slaughter. This reading is buttressed by the fact that live animals are included within the definition of livestock, 9 C. F. R. § 301.2rr, and that term is noticeably absent from 21 U. S. C. § 392(a).

Further support for this narrow reading of the MIA is found in the case of *United States v. Articles of Food … Buffalo Jerky*, 456 F. Supp. 207 (D. Neb. 1978). In that case, the government sought to condemn bison meat containing sodium nitrite and nitrate as adulterated within the meaning of the FDCA. The defendant there argued that the government was required to proceed against these articles under the MIA. The Court held that the action was maintainable under the FDCA, finding that in view of the limited nature of the MIA definition of meat food products, bison meat was not included therein. In comparing the two statutes, the Court noted:

> [T]he Meat Inspection Act is not intended to derogate from any authority conferred by the Federal Food, Drug and Cosmetic Act. See 21 U. S. C. § 679. Rather the Meat Inspection Act creates a separate area of concern — meat and meat byproducts for human consumption — over which the Department of Agriculture is given additional powers in the interest of protecting the public health and welfare.
>
> The Meat Inspection Act specifically delineates the food products subject to its provisions, listing only foods derived from cattle, sheep, swine, goats, and equines. Other food products are regulated under the FDCA. In view of the safeguards of testing and regulation of ingredients set forth in the comprehensive regulations pursuant to the FDCA, the court finds that the food products derived from bison meat will be adequately regulated for the protection of the public health and welfare under either the FDCA or the MIA. In an absence of a Congressional determination to include bison meat within the more limited coverage of the Meat Inspection Act, this court is unwilling to judicially extend the provisions of the Meat Inspection Act to do so.

456 F. Supp. at 210.

The defendant asserts that the case of *United States v. 2,116 Boxes of Boned Beef*, 516 F. Supp. 321 (D. Kan. 1981), is dispositive of the question before the Court. In that case, the government proceeded against boned beef which allegedly contained detectable levels of DES. The government brought that action under the Meat Inspection Act, specifically 21 U. S. C. §§ 601(m)(1), (m)(2)(A), (m)(3), 672. Defendant reads that case as holding that the Meat Inspection Act is the only act applicable to meat and live food producing animals which contain an unapproved drug. This Court does not agree.

In the *Boned Beef* case, the Court was not presented with the question whether the government could have proceeded against the meat based on the standards set forth in the Food, Drug and Cosmetic Act. Therefore, that case is inapposite to the one before the Court.

The defendant next cites this Court to two provisions of the MIA, arguing that they encompass application to live animals. 21 U. S. C. §§ 672, 673. These provisions give the U. S. Department of Agriculture [USDA] the authority to detain, seize, and condemn any "carcass, meat or meat food product of cattle … or any dead, dying, disabled or diseased cattle…." In defendant's view, these sections would be the proper authority for the government's actions against his veal calves.

First, as has already been determined, the calves in question are not meat, meat food products, or carcasses within the meaning of the MIA. Neither has either party asserted that these animals are dead, dying, disabled or diseased. However, assuming arguendo that these sections could form a basis for the government's actions in this case, they do not deny the government the authority to proceed against these animals under the provisions of the FDCA.

21 U. S. C. § 679(a) provides that "[n]otwithstanding any other provisions of law, including section 392(a) of this title, the provisions of this chapter shall not derogate from any authority conferred by the Federal Food, Drug and Cosmetic Act prior to December 15, 1967." The legislative history of this clause demonstrates that it was designed to "coordinate the FMIA and the FFDCA by providing that the provisions of the former shall not derogate from the authority conferred by the FFDCA prior to the enactment of [this amendment]." S. Rep. No. 799, 90th Cong., 1st Sess., reprinted in [1967] U. S. Code Cong. & Ad. News 2207. That report also stated:

> Sections 10, 403 and 409 of the MIA, as it would be amended by sections 10 and 16 of the bill, contains adulteration, misbranding and seizure provisions similar to those in the FFDCA and preserve the existing authority of the Secretary of HEW.
>
> The Secretary of Agriculture and the Secretary of HEW *would thus have concurrent jurisdiction* under the MIA and the FFDCA over meats and meat food products becoming adulterated or misbranded after inspection….

Id. at 2203 (emphasis added). Thus, even were this Court to hold that live veal calves were within the definition of meat or meat food products contained in the MIA, the government may still proceed against them under the FDCA. This is further supported by the affidavit of L. L. Gast, Associate Administrator, Food Safety and Inspection Service, United States Department of Agriculture.

Injunctive Relief

The standard in this Circuit for the grant of a preliminary injunction is that there be a

> showing of possible irreparable injury *and* either (1) probable success on the merits *or* (2) sufficiently serious questions going to the merits to make them a fair ground for litigation *and* a balance of hardships tipping decidedly toward the party requesting the preliminary relief.

Buffalo Courier Empress Inc. v. Buffalo Evening News, Inc., 601 F. 2d 48, 54 (2d Cir. 1979) (emphasis in original) (citations omitted). Because this is a proceeding under the FDCA, the government need not make a showing of irreparable harm. "The passage of the statute is, in a sense, an implied finding that violations will harm the public and ought, if necessary, to be restrained." *United States v. Diapulse Corp. of America*, 457 F. 2d 25, 28 (2d Cir. 1972). However, even if the violation of the statute was not an implied finding of irreparable harm, it would still be the finding of this Court that the government has demonstrated that the offer of these calves as slaughter for food would cause the public irreparable harm.

[*Adulteration*]

The government has charged the defendant with the "introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 21 U. S. C. § 331 (a). Having determined that the defendant's live veal calves are food, the Court must next determine whether they are adulterated and within interstate commerce.

21 U. S. C. § 342(a)(2)(D) defines adulterated food as food which "is, or it bears and contains, a new animal drug which is unsafe within the meaning of section 360(b) of this title." The government alleges that the calves on defendant's farm contain DES. DES is a new animal drug for which there is no approved application on file for use in veal calves. It is,

therefore, *per se* unsafe. If the government can show that the calves on defendant's farm contain DES, then it has met its burden of proving the animals adulterated under the FDCA.

DES is a synthetic hormone which, when administered to animals, is a growth promoter. DES also helps the animals to utilize their grain more efficiently, thus making them require less food. DES was routinely administered to cattle by farmers from the mid 1950's to 1979, when the FDA withdrew the approval of the application for its use for this purpose. The normal method of administration was by injection of pellets into the animal's ear. Thus, the drug was slowly released into the animal's system.

In 1979, the approval of the application for DES was withdrawn. This withdrawal was based on scientific evidence which showed that there was not a "no-effect level" for this drug in the edible tissues of the animals receiving the drug. Therefore, it was determined that it could not be said that the presence of this drug was safe at any detectable level in edible animal tissues. Since that time, there has been no approved use for DES in food producing animals. See generally Pl. Ex. 4.

In support of its argument that the animals on defendant's farm contain detectable levels of DES, the government points to the following facts: 1. Defendant offered two lots of veal calves in January 1983. When the livers and kidneys of five animals per lot were tested, detectable levels of DES were found. 2. On January 13, 1983, FDA investigators took fecal samples from defendant's farm. These samples, when analyzed, revealed detectable levels of DES. 3. Dr. Richard Condon and Dr. Nicholas Weber, scientists with the FDA, both opined that based on the presence of DES in the fecal samples, that DES is contained in the edible tissues of the calves on defendant's farm.

To the contrary, the defendant has suggested, through the testimony of his expert, Dr. Torrence Nett, that the fecal samples obtained by the FDA investigators could have been contaminated by possible DES residues contained in the moisture on the ceiling in the barn which may have fallen upon the manure. In this way, the test results can be interpreted as showing only that the manure contained DES, not that the calves contained DES.

This is an application for preliminary relief. The government need not prove at this point that the calves contained DES. Rather, all it need show is that there is a probable likelihood that such could be proved at trial. This it has done.

The defendant has certainly presented an interesting theory of contamination to the Court. However, his theory was undercut by the testimony of Dr. Nett at trial. When asked what he estimated to be the levels of DES in the edible tissues of these animals based on the presence of DES in the manure, Dr. Nett responded with a number, albeit a minuscule one, representing the level of DES present in the veal calves on defendant's farm. There is a probable likelihood that the calves on defendant's farm contain DES.

It is further the determination of this Court that there is a reasonable likelihood that the government can show at trial that the veal calves on defendant's farm are in interstate commerce. First the defendant stated that he often uses buyers who are outside the state to arrange for the purchase of veal calves. The defendant did not have with him the phase orders for the calves currently bring held on his farm. There exists the possibility that the government can show that these calves were not purchased within the state.

Second, even assuming that these calves were purchased within the state, there is still a reasonable likelihood that the government can prove that the animals are within interstate The defendant often offers his veal calves for slaughter to slaughterhouses which are involved in interstate commerce. In fact, the defendant has contacted such a slaughterhouse to inquire as to the price obtainable for the calves currently on his farm. Therefore, it cannot be said that these calves are not involved in interstate commerce. See *Katzenbach v. McClung,* 379 U. S. 241 (1964); *Houston E. & W. T. R. Co. v. United States,* 234 U. S. 342 (1913). This is especially true in light of the broad interpretation to be accorded this Act. See *United States v. Park,* 421 U. S. 658 (1975); *Drown v. United States,* 198 F. 2d 999 (9th Cir. 1952). The government, therefore, is entitled to injunctive relief based on its claim that the calves on defendant's farm are adulterated within the meaning of the FDCA. See 21 U. S. C. § 342(a) (2) (D)

[*Adulterating a Drug*]

As an additional ground for injunctive relief, the government accuses the defendant of adulterating a drug. See 21 U. S. C. § 351 (a) (5). The government contends that this drug has been involved in interstate commerce because there are no licensed manufacturer of the drug in the state. Therefore, it includes that the defendant must have obtained the drug in interstate commerce. Based on the proof currently in the record, this Court does not agree.

The government has not made any showing of where the drug allegedly used was manufactured. For all this Court knows, there may be no facility in the United States licensed to manufacture this drug. If this were true, then it could not be said that the drug *must have* passed through interstate commerce. Moreover, it is not clear to this Court that the defendant has himself administered DES to his calves. Indeed, the government's proof was directed to a showing that it was Mr. Vangenechten who administered the drug to the calves. The government has made no argument to this Court that Mr. Conhaim can be held responsible for this adulteration because of the actions of Mr. Vangenechten; there have been no agency allegations made. Therefore, the Court is a grant of injunctive relief on the government's contention that this drug adulterated.

[*Conclusion*]
Accordingly, the plaintiffs request for a preliminary injunction restraining the defendant from administering DES to any calves on his farm, enjoining defendant from offering for slaughter as food any calves which have been administered DES, and enjoining the defendant from offering for slaughter for food any veal calves currently on defendant's farm is granted.

IT IS SO ORDERED.

Footnotes

[1] United States Magistrate, sitting by designation. 28 U. S. C. § 636(c).

[2] Mr. Vangenechten has not been served in this case. At the start of the proof in this preliminary injunction hearing, the Court ordered that the complaint be dismissed as against Mr. Vangenechten.

End of Document

ATTACHMENT 2

FDA U.S. FOOD & DRUG ADMINISTRATION

USDA

October 22, 2019

The Honorable Jeff M. Witte
Secretary
Department of Agriculture
State of New Mexico
MSC 3189, Box 30005
Las Cruces, NM 88003-8005

Dear Secretary Witte:

This responds to your request to the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) for assistance in assessing the impact of groundwater contamination with certain per- and polyfluoroalkyl substances (PFAS), including perfluorooctane sulfonate (PFOS), at the Highland Dairy in Clovis, NM, on certain food produced there. FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act over food, including milk and live animals intended for food. USDA has regulatory authority under the Federal Meat Inspection Act over the meat products.

FDA analyzed the groundwater, silage, and milk produced at Highland Dairy and confirmed all were positive for PFAS contamination. In response, since the fall of 2018, FDA's Center for Food Safety and Applied Nutrition (CFSAN) has been working with you and your team at the New Mexico Department of Agriculture to assess the safety of milk produced by that operation.

To evaluate the potential safety concerns of beef that would be derived from affected dairy cattle at the Highland Dairy, USDA and FDA consulted with experts from the Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry to consider the available science and appropriate methodology for evaluating PFOS in muscle (beef). This work may need to be refined further as additional research and data on PFAS exposure and toxicity become available.

USDA analyzed blood samples taken from 179 dairy cattle at the Highland Dairy. PFOS was detected in every sample. In addition, USDA purchased 30 of the affected dairy cattle and moved them to New Mexico State University in Las Cruces, NM for a follow-up study.

FDA and USDA agree that, absent any further action to mitigate herd exposure, an evaluation of the data collected from the Highland Dairy, including PFOS levels detected in blood and tissues from the herd, support the determination that any affected cattle intended for food and meat derived from such cattle are considered adulterated and should not enter the food supply. Further, based on FDA's evaluation of the PFOS levels in milk, absent any further action to mitigate herd

exposure, milk from the affected cattle is considered adulterated and should not enter the food supply.

USDA has documented that removing affected cattle from exposure to PFOS causes the concentration of PFOS in the animals' blood and muscle tissue to decrease over time. FDA and USDA are currently evaluating the data to determine whether PFOS concentrations will decrease to a level where the affected cattle (and any meat potentially derived from such cattle) would no longer be considered adulterated under the applicable statutes. However, any decision on whether the adulterated affected cattle could enter the food supply shall only be made in consultation with FDA and USDA, and may require additional testing prior to, or immediately after, slaughter.

If you or the herd owner have additional questions, please contact Dr. Paul South, Division Director, Office of Food Safety, FDA/CFSAN at paul.south@fda.hhs.gov or Emilio Esteban, Chief Scientist, USDA Food Safety Inspection Service at emilio.esteban@usda.gov.

We look forward to working together on next steps and appreciate your patience as this joint work has been ongoing.

Sincerely,

Frank Yiannas
Deputy Commissioner Food Policy and Response
Food and Drug Administration

Mindy Brashears
Deputy Under Secretary for Food Safety
United States Department of Agriculture

Copy to:

Art Schaap – Highland Dairy