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The Role of Administrative Law in Regulating "Mad Cow Disease" as Explained in Creekstone Farms Premium Beef, LLC v. Department of Agriculture

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THE ROLE OF ADMINISTRATIVE LAW IN REGULATING "MAD COW DISEASE" AS EXPLAINED IN *CREEKSTONE FARMS PREMIUM BEEF, LLC V. DEPARTMENT OF AGRICULTURE*

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I. INTRODUCTION

The possibility of mad cow disease is enough to scare even the savviest of hamburger connoisseurs. The disease may go undetected by the average consumer, but the consequences can be deadly. As a result, the United States Department of Agriculture (USDA) has taken steps to protect American consumers against such risks. Under the authority of the Virus-Serum-Toxin Act (VSTA), the USDA has promulgated several regulations relating to the eradication of Bovine Spongiform Encephalopathy (BSE),[1] or mad cow disease.[2] Central to *Creekstone Farms Premium Beef, LLC v. Department of Agriculture*[3] is Creekstone's desire to test its cattle for BSE before shipping it to customers. However, the U.S. Court of Appeals for the District of Columbia Circuit held that the USDA's ban on the type of test used by Creekstone is valid.[4] This Comment first discusses the legal implications of VSTA and BSE. A discussion of the Court's analysis of the agency's interpretation of VSTA and its relationship to the petitioner Creekstone follows. Lastly, this Comment explores the implications of *Creekstone*'s holding on the cattle industry in the United States and abroad.

II. LEGAL BACKGROUND

A. *The Virus-Serum-Toxin Act*

Creekstone addresses the Virus-Serum-Toxin Act (hereinafter "VSTA" or the "Act"), which Congress enacted in 1913.[5] Congress initially passed VSTA to protect farmers from the sale of ineffective anti-hog cholera serum.[6] As set forth in the statute, VSTA bans the preparation,

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[1] Creekstone Farms Premium Beef, LLC v. Dep't of Agric., 539 F.3d 492, 493 (D.C. Cir. 2008).

[2] *Id.*

[3] *Id.*

[4] *Id.* at 503.

[5] *Id.* at 493.

[6] *Id.*

sale, barter, exchange and shipment of "any worthless, contaminated, dangerous or harmful virus, serum, toxin, *or analogous product* intended for use in the treatment of domestic animals."[7] Additionally, VSTA also states that "any virus, serum, toxin *or analogous product* manufactured within the United States and intended for use in the treatment of domestic animals" must be "prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding [a] license issued by the Secretary of Agriculture."[8] The Act further requires a permit from the Secretary for "any virus, serum, toxin, or analogous product for use in the treatment of domestic animals" that is imported.[9]

The Act gives the Secretary rulemaking authority in Section 154.[10] Section 154 states that the Secretary may "make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment . . . of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, *or analogous product* for use in the treatment of domestic animals, or otherwise to carry out [VSTA]."[11] The USDA utilized this authority and promulgated several regulations.[12]

Two of these regulations are at issue in *Creekstone*. The first regulation states that where the Administrator of USDA's Animal and Plant Health Inspection Service (APHIS) determines that the "protection of domestic animals or the public health, interest, or safety, or both, necessitates restrictions on the use of a [biological] product", then that product is subject to restrictions stated on the license.[13] The second regulation prohibits import into the United States of any biological product without a permit issued by the APHIS Administrator.[14] The regulations define "biological products" as including "all viruses, serums, toxins . . . *or analogous products* . . . which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response."[15] Additionally, the regulations define "treatment" as "the prevention, *diagnosis*, management, or cure of diseases of animals."[16]

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[7] 21 U.S.C. § 151 (2000) (emphasis added).
[8] *Id.* (emphasis added).
[9] 21 U.S.C. § 152 (2000).
[10] *See* 21 U.S.C. § 154 (2000).
[11] *Id.* (emphasis added).
[12] *Creekstone*, 539 F.3d at 494.
[13] *See* 9 C.F.R. § 102.5(d) (2001).
[14] *See* 9 C.F.R. § 104.1(a) (2001).
[15] 9 C.F.R. § 101.2 (2001) (emphasis added).
[16] 9 C.F.R. § 101.2(3) (2001) (emphasis added).

B. *History of BSE*

In the years preceding the present case, BSE emerged as a serious health concern.[17] Also known as "mad cow disease," it is defined by the court as an "invariably fatal neurological disease that causes degeneration of the cow's central nervous system."[18] According to scientists, it results when normally healthy proteins found in the nervous system of animals such as cattle become "abnormal."[19] These abnormal proteins are called prions.[20] Prions cause nerve cells in the cattle to "rupture, resulting in a loss of coordination and ultimately the death of the animal."[21] Typically, the disease passes from one animal to another through cow feed that includes the remains of BSE infected cattle, ruminant.[22]

BSE can infect humans who consume contaminated beef or beef products.[23] When humans contract the disease, it is known as variant Cruetzfeldt-Jakob Disease, or vCJD.[24] Scientists believe that BSE first originated in England where it was first diagnosed in 1986.[25] BSE has since been reported in at least twenty-five countries, including the United States.[26]

The USDA first attempted to control the spread of BSE to the United States in 1989 by banning the "importation of ruminant products from countries with known BSE-infected cattle."[27] In 1997, the ban expanded to include all ruminant feed for cattle.[28] Despite efforts by the USDA to prevent BSE from entering the country, three infected cows have been identified in the United States. [29] The first case occurred in 2003 in Washington State and involved an infected cow originating from Canada.[30] A second case was identified in Texas in June of 2005, and the third cow was located in Alabama in March of 2006.[31] In response to the existence of BSE in the U.S., several large cattle importers such as Japan, South Korea, and Mexico banned importation of all American beef.[32] While some

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[17] *Creekstone*, 539 F.3d at 495.
[18] *Id.* at 494.
[19] *Id.* at 494-495.
[20] *Id.* at 494.
[21] *Id.* at 495.
[22] *Creekstone*, 539 F.3d at 495.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Creekstone*, 539 F.3d at 495.
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.* at 496.

countries have lifted such restrictions, Japan and South Korea continue to restrict importation of American cattle.[33]

As a result of these infections, testing for BSE became necessary in the United States. In June 2004, APHIS initiated a 26-month program under which it tested 750,000 cattle for BSE.[34] Then, due to the low rate of infection, the USDA decided to lower the number of cattle to be tested.[35] In 2006, the USDA intended to test only 40,000 cattle, or roughly 1% of the cattle slaughtered per year.[36]

C. *Testing for BSE*

Several ways exist to test cattle for BSE.[37] The most common way is referred to as the "immunoassay," or the "rapid" BSE test.[38] This is the type of test the plaintiff intended to use.[39] However, there are several problems with the rapid BSE test.[40] First, the prions that identify BSE are only detected "if they exist in a relatively high concentration."[41] This limits the effectiveness of the test because the prions are only detectable two to three months before the cow begins to show physical signs of the disease.[42] Second, it is possible that the rapid BSE test will not even catch the disease before the cattle go to slaughter because of the long incubation period of the disease.[43] The incubation period is between two and eight years, which means that because the average cow is two years old at slaughter, it will not likely show a positive rapid BSE test.[44] Consequently, the USDA has concluded that use of this test is inefficient because of these limitations.[45] Moreover, the USDA has described the testing of clinically normal young cattle impractical, of no food safety value, and likely to produce false negative results.[46] However, the USDA has described the rapid BSE test as meaningful and reliable when used for surveillance purposes on animals exhibiting some type of clinical abnormality that could be consistent with BSE.[47]

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[33] *Id.*
[34] *Creekstone*, 539 F.3d at 495.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Creekstone*, 539 F.3d at 496.
[40] *Id.* at 495.
[41] *Id.*
[42] *Id.* at 496.
[43] *Id.*
[44] *Id.*
[45] *Creekstone*, 539 F.3d at 496.
[46] *Id.*
[47] *Id.*

III. CASE HISTORY

The petitioner in *Creekstone v. Department of Agriculture* was Creekstone Farms Premium Beef, LLC. Creekstone raises Black Angus cattle and slaughters almost 300,000 animals per year.[48] In response to the health emergency regarding BSE, Creekstone decided to test its cattle for the disease with the above-mentioned rapid BSE test kits.[49] However, when Creekstone attempted to purchase the test kits from Bio-Rad Laboratories, Inc., Bio-Rad informed Creekstone that USDA authorization was required before the tests could be sold.[50] In compliance with this requirement, Creekstone requested authorization on February 19, 2004, as well as in several later communications with the USDA.[51] Creekstone's requests were denied, and on March 17, 2004, the USDA issued a notice stating the rapid BSE test kits were only available to "USDA-approved laboratories."[52] It also stated the "distribution and use" of all BSE tests was under the control of the USDA.[53]

In a letter dated June 1, 2004, the USDA formally prohibited Creekstone from purchasing the BSE test kits.[54] The letter stated "[A]llowing a company to use a BSE test in a private marketing program is inconsistent with USDA's mandate to ensure effective, scientifically sound testing for significant animal diseases and maintain domestic and international confidence in U.S. cattle and beef products."[55]

Consequently, Creekstone filed suit based on three claims.[56] First, Creekstone argued that the USDA's regulation of biological products was *ultra vires*[57] because VSTA "provides no authorization at all for restrictions in the *use* of products."[58] Along the same lines, Creekstone claimed that the "definition of 'treatment' contained in regulation Section 101.2 goes 'beyond the scope of the rulemaking authority granted to USDA in the VSTA.'"[59] Second, Creekstone claimed that regulation concerning the rapid BSE tests are not used to "treat domestic animals" as required by VSTA because it does not "act primarily through the direct stimulation, supplementation, enhancement or modulation of the immune system or

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[48] *Id.* at 493.
[49] *Id.* at 496.
[50] *Id.*
[51] *Creekstone*, 539 F.3d at 496.
[52] *Id.* (quoting USDA, Center For Veterinary Biologics Notice No. 04-08 (March 17, 2004)).
[53] *Creekstone*, 539 F.3d at 496.
[54] *Id.* at 496-497.
[55] *Id.* (quoting Letter from Bill Hawkes, USDA, to John D. Steward, Creekstone Farms (June 1, 2004)).
[56] *Creekstone*, 539 F.3d at 497.
[57] BLACK'S LAW DICTIONARY 1559 (8th ed. 2004) (Ultra vires is defined as "Unauthorized: beyond the scope of power allowed or granted by a corporate charter or by law.").
[58] *Creekstone*, 539 F.3d at 497 (emphasis in original).
[59] *Id.*

immune response."[60] Third, Creekstone argued that the USDA's decision to deny it the right to use rapid BSE tests is "arbitrary and capricious" and a "violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A)."[61]

Both parties moved for summary judgment on Counts I and II, but neither moved for summary judgment on Count III.[62] On March 29, 2007, the lower court granted the USDA's motion for Count I and "upheld USDA's broad interpretation of 'treatment' in Sections 151-5 of the Act."[63] The court also granted Creekstone's motion in regard to Count II on the ground that the BSE tests are not used in the treatment of domestic animals because there is no cure for the disease.[64] Consequently, it held that "because testing can be done only post-mortem, rapid BSE test kits are not used for 'treatment' as that term is defined in 9 C.F.R. § 101.2(3)."[65]

III. ANALYSIS

A. *Holding*

The court held that the USDA acted within its authority delegated by VSTA by regulating biological products in the "use" of the treatment of domestic animals.[66] Consequently, a rapid BSE test kit, which is properly classified as a "biological product," may be restricted under VSTA.[67] The District of Columbia Circuit Court of Appeals employed de novo review in its consideration of the lower court's grant of summary judgment.[68]

B. *Count One: USDA's "Use" Regulations*

In its review of Count I, the Court addressed whether the BSE rapid test kits fall within the authority of the USDA's "use" regulations, which are found in 9 C.F.R. §§ 102.5(d) and 104.1.[69] The court phrased the issue as "whether USDA can regulate the use of biological products under VSTA."[70] The USDA's authority to regulate arises in two forms in Section 154.[71] First, the language of Section 154 gives the USDA rulemaking authority to promulgate "such rules and regulations as may be necessary to

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[60] *Id.*
[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] *Creekstone*, 539 F.3d at 497.
[65] *Id.*
[66] *Id.* at 503.
[67] *Id.*
[68] *Id.* at 497.
[69] *Id.* at 498 n.8.
[70] *Creekstone*, 539 F.3d at 498.
[71] *Id.*

prevent the preparation, sale, barter, exchange, or shipment . . . of any worthless, contaminated, dangerous, or harmful virus, serum, toxin or analogous product for use in the treatment in domestic animals."[72] Because this language is limited by the second clause requiring the products to be "worthless, contaminated, dangerous, or harmful," the court concluded that Section 154 did not authorize the USDA to regulate BSE rapid test kits.[73]

The court then proceeded to the second grant of authority found in Section 154, which authorizes the USDA to promulgate "such rules and regulations as may be necessary . . . otherwise to carry out this chapter."[74] The U.S. argued that the *Chevron* standard of review[75] should apply because of the broad language employed by the section to permit the regulation of biological products, but the court applied the *Skidmore*[76] analysis instead. [77] The court acknowledged that it usually analyzes agency interpretation cases under the more deferential *Chevron* doctrine.[78] However, it concluded "*Chevron* does not apply to the 'otherwise to carry out' language because that language was not added to the statute until 1985 . . . almost ten years after USDA promulgated the predecessor of Section 102.5(d)."[79] In addition, the court stated the "USDA may not reasonably rely on statutory language that did not exist when it first adopted its regulation."[80]

In applying the *Skidmore* analysis, Judge Henderson wrote that "[t]he weight [accorded to an administrative judgment] in a particular case will depend on the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control."[81] The court concluded that Section 102.5(d) did satisfy this *Skidmore* analysis[82] because the court concluded Section 102.5(d) "reflects considered agency deliberation," "has been consistently applied since 1976," and "is reasonably related to the purposes of VSTA, namely, to ensure the safety and efficacy of any product that is intended to be used in treating domestic animals."[83]

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[72] 21 U.S.C. § 154 (2000).

[73] *Creekstone*, 539 F.3d at 498.

[74] *Id.*

[75] *See* Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984).

[76] *See* Skidmore v. Swift & Co., 323 U.S. 134 (1944).

[77] *Creekstone*, 539 F.3d at 498.

[78] *Id.*

[79] *Id.*

[80] *Id.*

[81] *Id.* at 499, *quoting* U.S. v. Mead Corp., 533 U.S. 218, 228 (2001) (quoting *Skidmore*, 323 U.S. at 140 (second alteration in *Mead*)).

[82] *Creekstone*, 539 F.3d at 499.

[83] *Id.*

The court also deferred to the agency's interpretation of Section 104.1 because it found the USDA's interpretation "not inconsistent with the regulation."[84] Section 104.1 authorizes the Administrator to prevent biological products from entering the U.S. without a permit.[85] The court held that despite any express provision authorizing the Administrator to deny "an import permit based on the product's intended use (in this case, sales to Creekstone), USDA so interprets the regulation"[86] and the interpretation was held to be valid.[87]

Creekstone made several arguments in support of the USDA acting beyond its authority. First, it employed a doctrine of negative implication, *expressio unuis est exclusion alterius*, to suggest that "the omission of 'use' from VSTA's provisions precluded USDA from promulgating a 'use' regulation."[88] However, the court stated that this doctrine had "minimal, if any, application"[89] because of the broad language in the statute and the administrative nature of the proceedings. Second, Creekstone submitted that the "otherwise carry out" phrase in Section 154 could not support the "use" regulations because the "otherwise carry out" language was not added until almost a decade after the passage of the original statute.[90] However, the court quoted the district court when it stated that this theory "cuts both ways."[91] It concluded that "Congress's 1985 decision to leave section 102.5(d) undisturbed is 'persuasive evidence' that is it consistent with congressional intent."[92]

Creekstone made a third argument that the legislative history behind VSTA suggested that Congress only contemplated the regulation of "manufacturers and importers of biological products, not users like [itself]."[93] Despite its introduction of testimony during the 1913 House Committee on Agriculture that suggested the regulation was intended for other purposes, the court concluded that the legislative history regarding to VSTA is "extremely sparse"[94] and insufficient to support either interpretation.[95]

Lastly, Creekstone cited the House Conference Report for the Agriculture Bioterrorism Protection Act of 2002 (ABPA) to support its contention that VSTA lacks the authority to promulgate "use" regulations.[96]

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[84] *Creekstone*, 539 F.3d at 499.
[85] 9 C.F.R. §104.1 (2001).
[86] *Creekstone*, 539 F.3d at 499.
[87] *Id.*
[88] *Id.* at 500.
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Creekstone*, 539 F.3d at 500.
[93] *Id.* at 501.
[94] *Id.* (quoting Animal Health Inst. v. USDA, 487 F.Supp. 376, 378 (D.Co.1980)).
[95] *Creekstone*, 539 F.3d at 501.
[96] *Id.*

However, the court disagreed by stating that "the ABPA governs only those substances that 'pose a severe threat to plant or animal health,'" while VSTA governs all biological products.[97] The court further dismissed Creekstone's interpretation with its conclusion that Congress, in drafting ABPA, specifically exempt products already covered by VSTA from the authority of ABPA.[98]

The court found 9 C.F.R. § 102.5(d) to be a valid grant of authority to the USDA to impose restrictions on the use of a biological product.[99] Thus, the court concluded that the USDA may regulate the use of BSE tests.[100]

C. *Count Two: Meaning of "Treatment"*

Creekstone argued that the regulation of the rapid BSE test was not within VSTA's authority because the domestic animals were not being "treated" as required by Section 101.2.[101] While the district court agreed with this argument, the appellate court did not.[102] Contrary to the argument set forth by Creekstone and accepted by the lower court, Judge Henderson interpreted the term "treatment" broadly.[103] The court focused on Section 101.2's definition of "treatment," which explains that it is "the prevention, diagnosis, management *or* cure of diseases of animals."[104] Because the rapid BSE test kit need only meet one of these requirements, the court held that the test's use in diagnosing BSE was sufficient.[105] It also stated that the test "plays a valuable role in preventing and managing the spread of BSE" by "allow[ing] USDA to identify and destroy the remains of an infected cow, trace the spread of the disease and evaluate the success of its disease management measures."[106] The court was not persuaded by the argument that the test does not treat a cow once it has already been slaughtered because of these diagnostic purposes.[107] Thus, the court was satisfied that the USDA's interpretation was a reasonable reading of "diagnosis" as it is used in the definition of "treatment."[108]

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[97] *Id.*
[98] *Id.*
[99] *Id.* at 502.
[100] *Id.*
[101] *Creekstone*, 539 F.3d at 502.
[102] *Id.*
[103] *Id.*
[104] *Id.* (quoting 9 C.F.R. § 101.2 (2001) (emphasis added)).
[105] *Creekstone*, 539 F.3d at 502.
[106] *Id.*
[107] *Id.*
[108] *Id.*

Additionally, Creekstone attempted to use past statements by the agency to invalidate this characterization of the test kits.[109] In a rulemaking decision concerning the importation of Japanese beef in 2005, the USDA stated that "BSE testing of cattle at slaughter is not 'meaningful in the context of . . . animal health' and that the surveillance testing for BSE 'is not a [disease] mitigation measure.'"[110] The USDA further explained in this statement that the testing is not meaningful because it does "not produce meaningful results."[111] However, the court found that USDA's comment regarding meaningless results referred "only to blanket BSE testing and not to the efficacy of BSE testing when used on high-risk cattle only."[112] The court attempted to characterize the USDA's comment as one relating to BSE testing as a whole, as opposed to the particularized test in the present case.[113] In conclusion, the court found the USDA's definition of "treatment" in 9 C.F.R. § 101.2(3) to be reasonable.[114]

V. IMPLICATIONS

The holding of *Creekstone Farms Premiums Beef, LLC v. Department of Agriculture* essentially prevents Creekstone from testing its cattle in the manner that it sees fit. The court of appeals granted the USDA wide discretion in its interpretation of the VSTA. In fact, this was the main concern of Chief Judge Sentelle in his dissent.[115] He writes "...the Department exceeds the bounds of reasonableness in the interpretation assumed in its regulation."[116] Chief Judge Sentelle disagreed that the rapid BSE test kit falls within the phrase "analogous product" or that it is a form of "treatment" as mandated by the Act.[117] The dissent also refused to accept the conclusion that Section 154's "otherwise carry out" language encompasses the "use" of biological products.[118]

While several public policy arguments support the discretion awarded to agencies by courts, *Creekstone v. Department of Agriculture* seems to be an example of a court going too far. As emphasized by the dissent, an agency must act within the authority given to it from Congress

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[109] *Id.*

[110] *Id.*; *see* Importation of Whole Cuts of Boneless Beef from Japan, 70 Fed. Reg. 73,905, 73,914 (Dec. 14, 2005) (to be codified at 9 C.F.R. pt. 94).

[111] *Creekstone*, 539 F.3d at 502; *see* Importation of Whole Cuts of Boneless Beef from Japan, 70 Fed. Reg. 73,905, 73,914 (Dec. 14, 2005) (to be codified at 9 C.F.R. pt. 94).

[112] *Creekstone,* 539 F.3d at 503.

[113] *Id.*

[114] *Id.*

[115] *Id.* at 504.

[116] *Id.*

[117] *Id.*

[118] *Creekstone,* 539 F.3d at 504.

to prevent the possibility of a "roving commission."[119] The outcome appears to be inconsistent with the goal of the USDA. Instead of actively encouraging beef producers to safeguard their products, the agency is prohibiting Creekstone from voluntarily testing its cattle. Because the effects of BSE result in the loss of human life, it seems reasonable that the USDA would err on the side of caution and support companies like Creekstone that willingly accept added costs for the benefit of the consumer.

More importantly for Kentucky, the Commonwealth ranks twelfth in all cattle and calf production in the U.S.[120] With regard to beef cows, Kentucky ranks eighth in the country.[121] As a result, local slaughterhouses may be subjected to the same fate as Creekstone. Under this precedent, they will be similarly barred from proactive testing. It seems likely that the decision in favor of the USDA will be appealed and it is possible that the case will be overturned. Therefore, allowing private distributors to use rapid BSE test kits may be a possibility in the future.

VI. CONCLUSION

After *Creekstone*, private distributors are prevented from employing rapid BSE test kits without authorization from the USDA. The court accepted the agency's broad interpretation of VSTA in its promulgation of several regulations. In the end, the rapid BSE test kits have been lumped into the category of "treatment of domestic animals" because they have been characterized as "biological products." Consequently, the USDA remains the sole authority on who may test for BSE and in what manner, leaving Creekstone Farms without the option to privately test its own meat.

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[119] *Id.* (quoting BP West Coast Products, LLC v. FERC, 374 F.3d 1263, 1293 (D.C.Cir.2004) (quoting Michigan v. EPA, 268 F.3d 1075, 1084 (D.C.Cir.2001))).

[120] Ky. Dep't of Agric., *Kentucky Agricultural Statistics and Annual Report, 2006-2007*, *available at* http://www.kyagr.com/pr/agstats/index.htm.

[121] *Id.*