

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

CREEKSTONE FARMS PREMIUM BEEF, L.L.C.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. 06-0544 (JR)
	:	
U.S. DEPARTMENT OF AGRICULTURE, <i>et al.</i> ,	:	
	:	
	:	
Defendants.	:	

MEMORANDUM

Plaintiff Creekstone Farms Premium Beef, LLC wants to test every one of the approximately 300,000 head of cattle it slaughters each year to determine whether it was infected with bovine spongiform encephalopathy (BSE), commonly known as "mad cow disease." The United States Department of Agriculture (USDA), however, has denied plaintiff's request to purchase BSE test kits, asserting its authority under the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-159, (VSTA). The parties have cross-moved for summary judgment on the first two counts of plaintiff's complaint, which assert that the agency has exceeded its authority under the VSTA, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(C), by (1) promulgating regulations that are inconsistent with the VSTA, and (2) denying Creekstone's request to perform BSE testing on its own cattle.

BACKGROUND

BSE is a fatal, irreversible disease that causes progressive degeneration of the brain and central nervous system in cattle. The disease is caused by prions, abnormal proteins that cause normal cellular protein to convert to an abnormal form. The existence of BSE in an animal is confirmed through postmortem microscopic examination of the animal's brain tissue or by detection of the abnormal form of the prion protein in its brain tissue.

Experts generally agree that the same agent that causes BSE in cattle may cause a similar condition in humans known as variant Creutzfeldt-Jakob Disease (vCJD). Like BSE, vCJD is a neurodegenerative disease that is progressive, incurable, and fatal. Humans contract vCJD by consuming BSE-contaminated meat.

Approximately 190 people have died of confirmed cases of vCJD, almost all of them in the United Kingdom. Experts believe that BSE spread through the UK cattle herd through the consumption of feed contaminated with BSE-infected animal protein. In the past 20 years, BSE has spread from the UK to at least 20 other countries, including Canada and Japan.

In December 2003, a BSE-positive cow was found in the state of Washington. An investigation revealed that the cow was born in Canada and likely exposed to BSE there. Nevertheless, the discovery of BSE-infected cattle in the United States had a

substantial impact on the American beef export industry. Major export markets, such as Japan and South Korea, banned American-bred beef, causing a 75 percent decline in U.S. beef exports. Surveys in the United States and Japan showed that consumers were wary of U.S. beef because of fears about BSE.

USDA has implemented a number of measures designed to reduce the likelihood that BSE-infected beef will enter the U.S. food supply. USDA's Animal and Plant Health Inspection Service (APHIS) has conducted surveillance testing of U.S. cattle since 1990 in order to estimate the prevalence of BSE. Following the discovery of BSE within the U.S. in 2003, APHIS established an enhanced surveillance program, testing cattle identified as "high risk" - cattle older than 30 months, cattle exhibiting signs of central nervous system disorders, and cattle that could not walk. The enhanced surveillance program continued for 26 months and screened approximately 750,000 cattle. Only two positive cases were found. Current testing, performed exclusively by government-affiliated labs, screens approximately 40,000 cattle a year. Private testing is prohibited.¹

¹Other countries where BSE has been found test all or a significant portion of the cattle presented for normal slaughter. The European Union, for example, requires BSE testing not only for "at risk" or "suspect" cattle, but also for all apparently healthy cattle presented for slaughter for human consumption that are over 30 months of age. France, Italy, and Spain require testing of all cattle slaughtered at 24 months of age or over. Pl.'s Ex. 9, Report on the Monitoring and Testing of Ruminants for the Presence of Transmissible Spongiform Encephalopathy (TSE)

USDA's policy position is that testing only high risk cattle, as opposed to all cattle, is the most efficient method for detecting the presence of BSE. This is primarily because of the limits of existing BSE tests. The incubation period for BSE - the time from infection to outward manifestation of the disease - is two to eight years; the average period is five years. Only rarely do cattle younger than 30 months show any signs of the disease. The earliest point at which current testing methods can detect a positive case of BSE is two to three months before an animal would exhibit any external symptoms. Most cattle going to market in the United States are less than 24 months old. Therefore, BSE testing of slaughter-age cattle is unlikely to identify the disease, even in infected cattle, and USDA's position is that testing young cattle offers "no food safety value" and is "likely to produce false negative results." Decl. of Dr. Lisa Ferguson [#10-3] at ¶ 6.

Creekstone, a leading supplier of premium-quality beef products, alleges that it has lost substantial profits due to the reduced demand for U.S. beef. The bans in Japan and South Korea, for example, cost Creekstone \$200,000 per day in revenues when they were in effect. Although those bans were lifted in 2006, at

in the EU in 2005, European Commission, 20 June 2006, p. 8, Table 2. [#14-10]. Japan tests cattle of all ages at slaughter. Pl.'s Ex. 5, Japan-United States Working Group, at 9 [#6-7].

least partially, Creekstone contends that its profits continue to suffer due to consumer fears about BSE.

In order to address those fears, Creekstone decided to conduct its own testing of all of its cattle. It built a laboratory for BSE testing at its Arkansas City, Kansas, beef processing facility and sent employees to France for training on BSE testing procedures by Bio-Rad, Inc., which produces a BSE rapid screening test used by USDA, Japan, and other countries.

Creekstone also discussed purchasing test kits from Bio-Rad. In the course of those discussions, Bio-Rad informed Creekstone that USDA would only permit BSE testing as part of USDA's official surveillance program and would not permit the sale of test kits to Creekstone. Creekstone subsequently contacted USDA for approval, submitting a detailed BSE sampling, testing, and control procedure manual, and describing how the tests would be conducted and used.

On March 17, 2004, the USDA, through APHIS, issued Notice No. 04-08, which declared that the "sale and use" of BSE test kits would be restricted to laboratories approved by state and USDA animal health officials, and that the "distribution and use" of BSE test kits must be under the supervision of, and subject to conditions imposed by, USDA. As authority for that notice, USDA cited its regulations implementing the VSTA, specifically 9 C.F.R. §§ 104.1 - which requires a permit to

import "biological products" - and 102.5(d) - which authorizes "restrictions on the use of a product."²

In an April 8, 2004 meeting with Creekstone officials, USDA rejected Creekstone's request to perform BSE testing.³ The agency announced that decision in a press release the next day, and reiterated it in a June 1, 2004 letter to Creekstone. The letter cited as its reasons that "allowing 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

²Consistent with this policy, on March 4, 2004 USDA issued Bio-Rad a permit to import its BSE test kits into the United States, but required that "distribution and use" would be "under such conditions as" USDA may require, and that "sale and use" of the BSE test kits would be "restricted to laboratories approved by State and Federal (USDA) animal health officials."

³Several weeks earlier, in a February 26, 2004 statement to a reporter, Dr. Lisa Ferguson, Senior Staff Veterinarian at APHIS, suggested that Creekstone could face criminal prosecution under the VSTA if it were to test its cattle without prior USDA approval. A USDA spokesman subsequently stated that the agency did not mean to imply that Creekstone would be the subject of criminal penalties if it tested its cattle, but rather that any company that sold BSE test kits to Creekstone would be breaking the law. Decl. of John Stewart [#6-3] at ¶ 9.

international confidence in U.S. cattle and beef products.”⁴ On March 23, 2006, plaintiff filed this law suit.

The VSTA makes it unlawful to “prepare, sell, barter, or exchange...any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals” except at an establishment licensed by the Secretary of Agriculture. 21 U.S.C. § 151. The statute empowers the Secretary to establish a licensing regime and authorizes the Secretary to “make and promulgate from time to time such rules and regulations as may be necessary” to enforce the above prohibition, or “otherwise to carry out this paragraph.” Id. § 154. Violation of the VSTA is a misdemeanor punishable by a fine of up to \$1000 and/or imprisonment not exceeding one year. Id. § 158.

USDA has promulgated a series of regulations enacting the VSTA. Count I of Creekstone’s complaint asserts that these regulations unlawfully expand USDA’s authority beyond the scope of the VSTA. The first challenge is to 9 C.F.R. § 102.5(d), which asserts USDA’s authority to prescribe “restrictions on the use of a product.” Creekstone contends that the VSTA’s grant of

⁴At the suggestion of a USDA official, Creekstone, through Kansas State University, asked that USDA allow the university to designate Creekstone’s laboratory as a satellite laboratory, for the purpose of assisting the university in conducting BSE surveillance testing as part of USDA’s official network of BSE-testing laboratories. That request was rejected in August 2004.

authority to regulate viruses, serums, toxins, or analogous products covers only the preparation, sale, barter, or exchange of such products - not their "use." The second challenge in Count I is to the agency's inclusion of diagnostic tests within its definition of two key statutory terms, "analogous products" and "treatment." 9 C.F.R. § 101.2. Diagnostic tests cannot be regulated under the VSTA, in Creekstone's submission, because they are neither "analogous" to viruses, serums, or toxins, nor used "in the treatment of domestic animals," as required by the statute.

Count II of Creekstone's complaint challenges USDA's authority to regulate BSE test kits in particular. Creekstone claims that, even if USDA may regulate some diagnostic tests, it may not regulate BSE test kits, because they are not (1) a "virus, serum, toxin, or analogous product," nor (2) "intended for use in the treatment of domestic animals," nor (3) "worthless, contaminated, dangerous, or harmful."⁵

⁵Count III of the complaint, on which neither party has moved for summary judgment, asserts that USDA's actions, including specifically its refusal to allow plaintiff to purchase BSE test kits to test its own cattle, are arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A). The parties agree that summary judgment on either of the first two counts of Creekstone's complaint would be dispositive of Count III.

ANALYSIS

I. Mootness and standing

At the outset, the government asserts that this case was mooted by Japan's decision in July 2006 to resume imports of U.S. beef, and that plaintiff lacks standing, because the alleged injury it claims - diminished sales - is not likely to be redressed by permitting plaintiff to conduct BSE testing on all of its cattle. These assertions, however, rely on an unduly narrow view of plaintiff's complaint.

As to mootness: Creekstone alleges that USDA's actions have harmed its sales in Japan "and other foreign markets," and that Creekstone could increase U.S. sales if it were permitted to conduct BSE testing on its cattle. Compl. ¶ 5. The lifting of Japan's ban on U.S. beef is not an "intervening event[]" that makes it "impossible to grant the prevailing party effective relief." Burlington Northern R.R. Co. v. Surface Transp. Bd., 75 F.3d 685, 688 (D.C. Cir. 1996).

As to standing: Creekstone alleges that its revenues have dropped 35 percent because of concerns about BSE. Its customers say they would buy more Creekstone beef - and pay a higher price - if it were tested for BSE. Supp. Decl. of John B. Stewart. [#14-2] at ¶¶ 3, 7. Creekstone has alleged a concrete and particularized injury that is actual, traceable to enforcement of the USDA's prohibition on BSE testing by private industry, and redressable by this Court. See Utility Air

Regulatory Group v. EPA, 320 F.3d 272, 277 (D.C. Cir. 2003);
Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992).

II. Count I - Challenge to USDA Regulations

A. Restrictions on the use of biological products

The VSTA authorizes the Secretary of Agriculture to enact regulations "as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid 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 this chapter...." 21 U.S.C. § 154 (emphasis added). The USDA refers to viruses, serums, toxins, and analogous products as "biological products" and has instituted a licensing regime for "[e]very person who prepares biological products" subject to the VSTA. The USDA asserts authority to prescribe "restrictions on the use of a product," including "limits on distribution of the product." 9 C.F.R. § 102.5(d). That regulation is the asserted basis for USDA's decision to prohibit Creekstone's "use" of a biological product for private BSE testing.

Creekstone contends that USDA's "use" regulation exceeds its authority to regulate "preparation, sale, barter, exchange, or shipment," but Creekstone's reading of the statute is too narrow. The principle of *expressio unius est exclusio alterius* will not restrict the application of a statute that also contains expansive modifiers such as "as may be necessary to

prevent" and "or otherwise to carry out this chapter."⁶ Compare NLRB v. Beverly Enterprises-Massachusetts, Inc., 174 F.3d 13, 32 (1st Cir. 1999) (holding that terms of 29 U.S.C. § 156 authorizing the NLRB "to make such rules and regulations as may be necessary to carry out the provisions of the Act" grant the NLRB "broad rulemaking authority") (emphasis added). See also United States v. O'Hagan, 521 U.S. 642 (holding that the phrase "means reasonably designed to prevent" expanded the SEC's authority beyond those acts specifically enumerated in the statute.)

Plaintiff goes on to note that the agency has not, at least until recently, explained the reasoning behind its interpretation of the VSTA, and argues that an agency's interpretation of a statute is not entitled to deference under

⁶Plaintiff contends that USDA may not rely on the "or otherwise to carry out this chapter" language, because it was only added to the VSTA in 1985, nine years after USDA's promulgation of the regulation. Yet that argument cuts both ways. Because Regulation 102.5(d) was already in effect when Congress amended the VSTA, Congress had an opportunity to change the law so as to preclude USDA's interpretation, and yet instead expanded USDA's authority by adding the "or otherwise to carry out this chapter" language. This could be considered an implicit endorsement of the regulation. See Public Citizen, Inc. v. F.A.A., 988 F.2d 186, 194 (D.C. Cir. 1993) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change.") (quoting Albemarle Paper Co. v. Moody, 422 U.S. 405, 414 n.8 (1975)). Although there is no indication that Congress intended to ratify the agency's interpretation, as required for the so-called reenactment doctrine, there is also no indication that Congress at any point disagreed with the agency's interpretation of its powers.

Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984), if not explained. See Public Citizen, Inc. v. U.S. Dept. of Health and Human Services, 332 F.3d 654, 662 (D.C. Cir. 2003) (citing Adamo Wrecking Co. v. United States, 434 U.S. 275, 287 (1978)). What plaintiff fails to note here is that the agency remains entitled to a "degree of deference," under Skidmore v. Swift & Co., 323 U.S. 134 (1944), so long as its interpretation has "the power to persuade." Public Citizen, 332 F.3d at 662, citing Christensen v. Harris County, 529 U.S. 576, 587 (2000). Given the VSTA's expansive language, the agency's interpretation is more persuasive than the narrow reading espoused by plaintiff.⁷

There is some legislative history, albeit some 95 years old, that further supports the agency's position: The 1913 Senate Report that accompanied the VSTA states that the statute was enacted "also for the purpose of controlling the use, by preventing the interstate shipment, of similar dangerous and worthless products that may be manufactured within the United States." S. Rep. No. 62-1288, at 2 (1913) (emphasis added).

B. USDA authority to regulate diagnostic testing

USDA is also entitled to deference with regard to the second challenged regulation, 9 C.F.R. § 101.2. That regulation

⁷For the same reasons, plaintiff's motion for summary judgment as to 9 C.F.R. § 104.1 - which extends USDA's restrictions to the importation of biological products - also fails.

defines the terms "biological product,"⁸ "analogous product,"⁹ and "treatment"¹⁰ so as to allow the agency to regulate diagnostic tests and diagnostic test components. Although the parties agree that a diagnostic test is not a "virus, serum, [or] toxin" under the VSTA, they disagree as to whether it may be an "analogous product."

Plaintiff asserts that USDA may not regulate substances, such as diagnostic tests, that are "intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity," 9 C.F.R. § 101.2, because such substances do not involve an immune response or the immune system, and so are not "analogous" to a "virus, serum, [or] toxin." Pl.'s Mem. [#6] at 29-30. The government, conversely, contends that diagnostic test kits "frequently rely on the interaction of antibodies and antigens to stimulate, modulate, or detect the immune system of an animal, as do products made with viruses, serums, or toxins." Def.'s Mem. [#10] at 36; Decl. of Dr. Byron Rippke [#10-4] at ¶ 5-6. Whether

⁸The term "biological products" includes "diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances." 9 C.F.R. § 101.2.

⁹ The term "analogous products" includes "Substances...intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity." 9 C.F.R. § 101.2.

¹⁰The term "treatment" means "the prevention, diagnosis, management, or cure of diseases of animals." 9 C.F.R. § 101.2.

a diagnostic test is sufficiently analogous to a virus, serum, or toxin so as to support regulation under the VSTA is not a matter for this Court to decide. Where, as here, an agency's interpretation of a statute is based on its own scientific expertise, judicial deference is warranted. See Troy Corp. v. Browner, 120 F.3d 277, 283 (D.C. Cir. 1997) (showing "considerable deference...where the agency's decision rests on an evaluation of complex scientific data within the agency's technical expertise."); National Committee for the New River v. F.E.R.C., 373 F.3d 1323, 1327 (D.C. Cir. 2004) ("When an agency is evaluating scientific data within its technical expertise, an extreme degree of deference to the agency is warranted.") (internal quotations and citations omitted).¹¹

Plaintiff's reliance on Lubrizol Corp. v. EPA, 562 F.2d 807 (D.C. Cir. 1977), is misplaced. In that case, the Court of Appeals struck down EPA's interpretation of the Clean Air Act's requirement to register "any fuel or fuel additive" as extending

¹¹Plaintiff argues that USDA's interpretation is "entitled to no weight," because USDA did not assert authority over diagnostic tests until more than sixty years after the passage of the VSTA. Pl.'s Mem. At 31. I am not certain when the words "antigens, antibodies, [and] nucleic acids" entered the lexicon, but I am quite sure that this argument of plaintiff overstates the law. Although the Supreme Court gives "great weight to the contemporaneous interpretation of a challenged statute by an agency charged with its enforcement," Bankamerica Corp. v. U.S., 462 U.S. 122, 130 (1983), plaintiff has cited no case law suggesting that the inverse is true as well. Indeed, a rule requiring agencies to adopt regulations simultaneously with the passage of legislation would prevent them from adapting to scientific advancements over time.

to additives for use in motor vehicle engine oil. EPA's rationale was that regulation of oil additives, which contribute substantially to motor vehicle emissions, furthered the goals of the Act. The court concluded that such regulation might well be warranted "as a policy matter...[but] that showing by itself is not sufficient to prompt us to substitute the agency's albeit well meaning interpretation for the clear language that Congress wrote into the statute." Id. at 819. The Clean Air Act did not contain the VSTA's expansive and ambiguous phrase "or analogous products." It is that phrase which gives USDA the authority reasonably to regulate, not only viruses, serums and toxins, but also a broader universe of similar products.

III. Count II - USDA Authority to Regulate BSE Test Kits

The VSTA thus gives the USDA authority to regulate the "use" of "analogous products" including diagnostic tests. The authority only extends, however, to products that are:

- (1) "intended for use in the treatment of domestic animals," and
- (2) "worthless, contaminated, dangerous, or harmful."¹² 21

U.S.C. § 154. Count II focuses on the question whether the BSE test kit is such a product.

¹²Plaintiff also challenges USDA regulation of BSE test kits on the basis that they are not "analogous" to a virus, serum, or toxin. This challenge essentially rehashes plaintiff's arguments about diagnostic tests in general, and fails for the same reasons those arguments failed.

USDA has defined "treatment" as "the prevention, diagnosis, management, or cure of diseases of animals." 9 C.F.R. § 101.2(3). Whether diagnosis should generally be considered an aspect of treatment, as opposed to something altogether separate, is a question on which the parties and their experts disagree, but the government has put forth a plausible argument in support of its interpretation, and that interpretation is entitled to deference.¹³

Similar deference will not be given, however, to USDA's argument that BSE test kits are used for treatment. There is no known treatment or cure for BSE, Rippke Decl. ¶ 10, and BSE test kits are used only on animals that are dead. Even if USDA is correct that diagnosis in general is "an inherent and crucial aspect of treatment," Rippke Decl. ¶ 11, USDA's own pronouncements about BSE test kits establish that they have nothing to do with "treatment" of BSE. USDA's position is that BSE testing of cattle at slaughter is not "meaningful in the

¹³*Amicus Curiae* Wild Oats Markets, Inc., a retailer of natural and organic food, argues that USDA's prohibition on private BSE testing "implicates the First Amendment rights of food retailers and consumers because the purpose and inevitable effect of that ban is to prevent retailers from communicating information on products it sells, and to prevent customers from receiving it." Mot. for Leave to Appear as Amicus Curiae in Opp. to Defs.' Mot. for Summ. J. (#17) at 5. That argument is rejected. The USDA has not attempted to regulate speech or expression, but only non-expressive conduct - the sale of BSE test kits to private beef processors such as Creekstone. Compare United States v. O'Brien, 391 U.S. 367, 377 (1968) (setting forth balancing test for when Congress may regulate conduct with expressive content).

context of...animal health" and that surveillance testing for BSE "is not a [disease] mitigation measure." USDA APHIS, "Importation of Boneless Cuts of Beef from Japan," 70 Fed. Reg. 73,905, 73,914 (Dec. 14, 2005).

It is unnecessary to reach the question of whether BSE test kits are "worthless," because their use may not be regulated under the VSTA unless they are both "intended for use in the treatment of animals" and "worthless." The government may indeed be right that the tests are "ineffective, misleading, and essentially worthless...when used, as proposed by plaintiff, to diagnose the disease in all slaughter-aged normal-looking cattle." Def.'s Mem. at 42. But, should a reviewing court determine that BSE could be detected in slaughter-age cattle, as is suggested by evidence put forward by plaintiff and the more extensive testing conducted by other countries, let it be noted that the government cannot have it both ways: the test kits cannot be both "used for treatment" and "worthless." If USDA's surveillance testing helps "manage" the disease by providing information about the prevalence of BSE and contributing to the knowledge of the disease, see Defs.' Reply at 19-20, citing 9 C.F.R. § 101.2(3) (defining "treatment" to mean "the prevention, diagnosis, management, or cure of diseases of animals") (emphasis in original), then so might the more extensive testing proposed by Creekstone.

In any event, evaluation of "worthlessness" (*vel non!*) is best left to the apostles of law and economics, who might find a formula for deciding whether USDA is right, that BSE testing of seemingly healthy cattle at normal slaughter age has neither scientific value¹⁴ nor any value to consumers, because it is likely to produce false negative results that could mislead the public¹⁵ - or Creekstone is right, that USDA's decision to conduct less extensive testing than other countries has left U.S. companies at a competitive disadvantage, and thus that private testing could be valuable to a seller of cattle - or I am right, that the consumer issues at the heart of USDA's position cannot be located within the purposes of the VSTA, and appear to lie, not with USDA, but with the Federal Trade Commission, or perhaps the Commerce Department.

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An appropriate order accompanies this memorandum.

JAMES ROBERTSON
United States District Judge

¹⁴The government's additional argument, that private testing somehow would interfere with USDA's surveillance program, is unexplained and therefore rejected.

¹⁵Of greater concern is the possibility that private testing could produce a false positive result, which might trigger unnecessary public alarm. USDA has asserted this possibility as a reason to avoid private testing. Indeed, the Bio-Rad kits that Creekstone proposes using are used throughout the world, including as part of the USDA's own surveillance testing.