Order Code RL32414

The Private Testing of Mad Cow Disease: Legal Issues

Updated December 3, 2004

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Summary

The positive identification of bovine spongiform encephalopathy or BSE, commonly known as "mad cow disease," in a Washington State cow in December of 2003 sparked a number of reactions from the federal government, the meat industry, and close to forty countries world-wide. The U.S. Department of Agriculture (USDA), for example, announced a one-time extensive BSE sampling and surveillance program designed to test as many high-risk cattle as possible over a 12 to 18-month period with the assistance of designated state and university diagnostic laboratories across the country. USDA implemented the new program in June of 2004, and uses USDA-approved "rapid" immunologic test kits.

Most countries, however, quickly banned the importation of United States beef following the announcement. Japan, for instance, previously insisted that the United States test *all* of its cattle for the fatal disease at slaughter before it would allow the beef to enter its borders, but announced in October of 2004 that it would allow some U.S. beef to enter the country under an interim trade program. Nonetheless, in an effort to meet new consumer demand, some private slaughterers propose to test 100% of their cattle using USDA approved "rapid test" kits. For example, Creekstone Farms Premium Beef, a private specialty producer and processor of Black Angus Beef, sought approval from the USDA to conduct voluntary BSE rapid testing for all the cattle it processes in order to promote sales, especially exports. The USDA, however, rejected Creekstone's request primarily because the test had only been licensed for animal health "surveillance" purposes and "the test as proposed by Creekstone would have implied a consumer safety aspect that is not scientifically warranted."

The USDA's rejection of Creekstone's request to privately test all of its cattle for BSE has ignited a significant amount of debate among lawmakers and segments of the beef industry. At issue is whether the USDA's decision to reject Creekstone's request to test all of its animals for BSE was a valid agency action. This report analyzes the legal authority of the USDA's Animal and Plant Health Protection Service to regulate *all* testing for BSE, particularly the voluntary testing of 100% of a *private* company's animals with rapid test kits. This analysis also discusses the USDA's recent rejection of Creekstone's application to test *all* of the cattle it processes for BSE.

This report does not discuss the possible role that the Food and Drug Administration may play in the regulation of BSE testing and surveillance, nor does it discuss the jurisdictional issues associated with the potential litigation that may arise from the Creekstone decision. For information on USDA, FDA, and legislative activities relating to BSE, please see CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*. This report will be updated as warranted.

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Background

Historically, the federal government has assumed primary responsibility for the management and testing for foreign animal diseases[1] like bovine spongiform encephalopathy or BSE, commonly known as "mad cow disease." States and veterinarians have played a role in animal disease testing but usually with significant federal oversight. The U.S. Department of Agriculture (USDA) announced a one-time extensive BSE sampling and surveillance program designed to test as many cattle in the targeted high-risk population as possible over a 12 to 18-month period with the assistance of designated state and university diagnostic laboratories across the country.[2] The USDA's surveillance plan will also obtain a random sample of normal, but older animals at slaughter.[3] USDA implemented the new program in June of 2004, and uses USDA-approved "rapid" immunologic test kits.[4] Rapid tests are designed to determine the presence of abnormal BSE-related proteins within a few hours—a dramatic difference from the international "gold standard" test for BSE: the immunohistochemistry test, which can take up to two weeks.

Some countries, like Japan, saw USDA's proposed sampling as inadequate and previously insisted that the United States test *all* of its cattle for the fatal disease at slaughter before it would allow the beef to enter its borders. Japan placed a ban on U.S. beef since the first case of BSE was diagnosed in Washington state in December of 2003, but announced in October of 2004 that it would allow some U.S. beef to

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[1] Foreign animal disease are important transmissible livestock or poultry diseases believed to be absent from the United States that can have potentially significant health or economic impacts.

[2] USDA estimates that 250,000 to 400,000 samples could be tested during a one-year collection period. The targeted high-risk populations include cattle that are exhibiting central nervous system disorders, nonambulatory cattle (downers), and those that die on the farm of unknown causes. *See* USDA, *Bovine Spongiform Encephalopathy (BSE) Surveillance Plan* (March 15, 2004) *available at* [http://cofcs66.aphis.usda.gov/lpa/issues/bse/BSE_Surveil_Plan03-15-04.pdf].

[3] *Id.* The BSE disease can take years to develop from exposure to clinical signs; consequently, it is argued that only older animals (i.e., animals approximately 30 months and older) are an appropriate population for BSE surveillance testing.

[4] USDA anticipates reaching full testing capacity around the first part of July 2004. Statement by Dr. Ron DeHaven, Administrator of APHIS, *Technical Briefing*, Release No. 0204.04, (May 21, 2004).

enter the country under an interim trade program.[5] Japan usually imports about $1 billion annually of U.S. beef.[6] Creekstone Farms Premium Beef, a private specialty producer and processor of Black Angus Beef, reportedly sought approval from the USDA to conduct voluntary BSE rapid testing for all the cattle it processes under a "marketing" program. Japan represents 20% of Creekstone's sales.[7]

On April 8, 2004, the USDA rejected Creekstone's request primarily because the test had only been licensed for animal health "surveillance" purposes and "the test as proposed by Creekstone would have implied a consumer safety aspect that is not scientifically warranted."[8] The USDA's rejection of Creekstone's request to privately test all of its cattle for BSE with rapid test kits has ignited a significant amount of debate among lawmakers and segments of the beef industry. At issue is whether the USDA's decision to reject Creekstone's request to test all of its animals for BSE was a valid agency action. This necessarily calls into question USDA's general authority to regulate the voluntary private testing for BSE.

USDA Authority

The USDA cites the Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. §§151-159) (hereinafter VSTA) and its applicable regulations as the source of authority for its regulation of animal testing and, more particularly, the licensing of rapid test kits.[9] The VSTA was originally enacted in 1913 primarily in response to substantial losses being suffered by American hog raisers from the unregulated manufacture and distribution of anti-hog cholera serum.[10] The stated purpose of the VSTA in 1913 was to prevent:

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[5] Under the proposed interim program, Japan would allow only beef products from cattle of 20 months or younger to be imported; the United States would agree to expand the definition of cattle parts that have a higher risk of harboring the BSE agent; and, the United States would permit Japanese specialty beef and products into its market. Because numerous details must be negotiated before any agreement is final, and because both countries must conduct potentially lengthy rulemaking before implementation, most observers do not expect that U.S. beef will be eligible for the Japanese market until well into 2005. For more information, see CRS Report RS21709, *Mad Cow Disease and U.S. Beef Trade.*

[6] Scott Kilman, *Beef Firm Plans Mad-Cow Tests in Challenge to U.S. Standards*, THE WALL STREET JOURNAL ONLINE, February 27, 2004.

[7] Sally Schuff, *Creekstone Farms debate centers on issue of marketing versus food safety*, FEEDSTUFFS, April 19, 2004.

[8] USDA Statement by Bill Hawks, Undersecretary for Marketing and Regulatory Programs Regarding a Request by Creekstone for Private BSE Testing, Release No. 0141.04 (April 9, 2004).

[9] Jon Ortiz, *State looks to test beef: Lawmakers hope to soften foreign ban,* SAC BEE (an Online Division of THE SACRAMENTO BEE), March 12, 2004, available at [http://www.sacbee.com/content/business/agriculture/story/8491741p-9420617c.html].

[10] Hall v. State, 158 N.W. 362 (Neb. 1916).

> the introduction into the United States of dangerous and worthless viruses, serums and analogous products for use in the treatment of domestic animals, some of which products may be the means of introducing disease not now known in the United States, and 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.[11]

The USDA found this legislation necessary "in order to protect the farmer and stock raiser from improperly made and prepared serums, toxins, and viruses."[12] Congress amended the VSTA in the Food Security Act of 1985 (P.L. 99-198, Tit. XVII, §1768) to (1) authorize the USDA to license and regulate *intra*state movement of biological products, (2) broaden the Secretary's authority to issue regulations "to carry out the act," (3) grant the agency enhanced enforcement powers, and (4) recognize a congressional finding that federal regulation was "necessary to prevent and eliminate burdens on commerce and to effectively regulate such commerce."[13] The legislative history supporting the 1985 VSTA amendments reflects a congressional understanding of the need for "national uniform standards" in the preparation and sale of biological products.[14]

Except as permitted in the act, the VSTA makes it unlawful for any person to prepare, sell, barter, or exchange anywhere in the U.S., or to ship or deliver in or from the U.S., any dangerous or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals.[15] The VSTA further requires that a person who prepares, sells, barters, exchanges, or ships any virus, serum, toxin, or analogous product do so in compliance with USDA regulations through an establishment holding an unsuspended and unrevoked USDA license.[16] The VSTA authorizes the Secretary to issue, suspend, and revoke licenses for the maintenance of establishments that prepare viruses, serums, toxins, or analogous products for use in the treatment of domestic animals. Pursuant to 21 U.S.C. §152, the VSTA also prohibits the importation of any virus, serum, toxin, or analogous product except under a permit from the Secretary of Agriculture.

The Secretary of Agriculture is also authorized to make and promulgate rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment of a dangerous virus, serum, toxin, or analogous product for use in the treatment of domestic animals or otherwise to carry out the VSTA. Pursuant to this authority, the USDA, through the Animal and Plant Health Protection Service (APHIS), has promulgated a comprehensive set of regulations governing the licensing of viruses, serums, toxins, or analogous products (See 9

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[11] S.Rept. 62-1288 (1913) (3rd Sess.).

[12] *Hearing before the Committee on Agriculture on the Estimates of Appropriations for the Fiscal Year Ending June 30, 1914*, (H.R. 28283) 62nd Cong. 24 (1913) (statement of Dr. A. M. Farrington, Asst. Chief Bureau of Animal Industry, Dept. of Agriculture).

[13] *See* 21 U.S.C. §§151, 154, 159.

[14] S.REPT. 99-145 at (1985).

[15] 21 U.S.C. §151.

[16] *Id.*

C.F.R. subchapter E, pts. 101 to 124). Regulations for the VSTA broadly catagorize viruses, serums, toxins, or analogous products as "biological products" at any stage of production 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. A "biological product" includes but is not limited to:

> vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and *diagnostic components*, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.[17] (italics added)

"Treatment" under the regulations means the prevention, diagnosis, management, or cure of diseases of animals.[18] "Prepare" or "preparation" is generally referred to as the manufacture or production of a biological product and has been defined as the steps and procedures used in the processing, testing, packaging, labeling, and storing of a biological product. With respect to licensing, the regulations require every person who "prepares" biological products subject to the VSTA to have a valid U.S. Veterinary Biologics Establishment License and at least one valid U.S. Veterinary Biological Product License.[19] A USDA permit is also required for every person importing a biological product.[20]

While the VSTA explicitly addresses the preparation, sale, barter, exchange and shipment only, USDA regulations (discussed below) authorize "use" and "distribution" restrictions in the public interest or for the protection of animals.

Analysis

The USDA's rejection of Creekstone's request to privately test all of its cattle for BSE with rapid test kits has sparked a considerable amount of controversy. At issue is whether the USDA's decision to reject Creekstone's request to test all of its animals for BSE was a valid agency action. As such, we first examine how a rapid test kit may fall within APHIS's regulatory purview. Next, we address APHIS's purported authority over private companies intending to conduct voluntary rapid tests for BSE. Finally, we discuss the validity of the USDA's decision in the Creekstone case.

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[17] 9 C.F.R. §101.2.

[18] *Id.*

[19] *Id.* at §102.2.

[20] *Id.* at §104.1.

Rapid Test Kits

In response to the need for an increase in BSE testing, the USDA and some private beef producers have developed plans to use BSE rapid test kits. In order for APHIS to regulate the proposed rapid test kits, however, it must be demonstrated that such tests fall within the regulatory purview of the federal agency (i.e., they must be a "biological product.") Pursuant to APHIS regulations, rapid test kits may be considered "biological products" if they are shown to be "diagnostic" tests "prepared" for and used in the "treatment" of cattle.[21] In addition or in the alternative, one could also argue that a rapid test kit, as a test prepared and intended to detect an animal disease, may be an "analogous product." "Analogous products" are considered "biological products" when the item in question at any stage of production or distribution resembles a biological product intended for use in the treatment of animals through appearance or representations.

The applicability of the aforementioned regulations seem to make USDA's authority over the manufacture and distribution of rapid test kits reasonably clear. Furthermore, these applications seem consistent with APHIS's overarching mission under the VSTA (and other laws) to protect U.S. public and agricultural health by assuring that biologics used in the treatment of animals are pure, safe, potent, and efficacious.[22] As such, it would appear that any person wishing to manufacture, distribute, or sell rapid test kits would need the appropriate USDA licenses or demonstrate that they do not fall within the reach of the federal regulations. In fact, the USDA has reportedly licensed at least four different companies' rapid test kits.[23] What is not entirely clear, however, is whether the USDA has the authority to selectively license the rapid test kits for particular purposes and in essence, keep BSE testing solely a federal responsibility.

Private Testing

As mentioned above, the USDA has reportedly only licensed rapid test kits for "surveillance" purposes. This limitation has restricted the ability of private entities to obtain kits. At the center of the debate is a proposal from Creekstone to privately test for BSE 100% of the cattle it processes. The tests, however, would be for reportedly "marketing" purposes rather than the USDA approved, "surveillance" purpose. The USDA claimed that Creekstone's proposal had an implied consumer

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[21] Moreover, USDA's approval of the rapid test kits as "surveillance" tools appears consistent with its regulatory definition of "treatment," which includes the "diagnosis" and "management" of animals.

[22] Viruses, Serums, and Toxins and Analogous Products; Restrictions on Distribution and Use, 57 Fed. Reg. 38758 (Aug. 27, 1992).

[23] *First BSE rapid tests approved for USDA surveillance plan*, FEEDSTUFFS, March 29, 2004 (HerdCheck's IDEXX BSE Antigen Test Kit & Bio-Rad's TeSeE test); *Prionics and Roche Gain Approval of Rapid BSE Tests for USDA*, PR Newswire, April 8, 2004 (Prionics(R)-Check Western and Prionics(R)-Check LIA (distributed by Roche Diagnostics)); *Abbot Laboratories Receives Approval From U.S. Department of Agriculture for Rapid Enfer BSE Test*, PR Newswire, April 7, 2004 (Abbot Laboratories' Rapid Enfer BSE test).

safety aspect that was not scientifically warranted and denied Creekstone's request to use rapid test kits. We could not determine exactly which licenses or permits a private company intending to "use" BSE rapid test kits would need pursuant to federal regulations (see Creekstone discussion).[24] The authority under which APHIS can regulate the actual "use" of a licensed rapid test kit seems to be less clearly defined than its authority over the actual preparation of such a biological product.

In determining whether an agency action is valid, a reviewing court examines the bounds of authority granted to the agency by Congress.[25] In *Chevron v. Natural Resources Defense Council*, the Supreme Court established a two part test to assess the validity of an agency's interpretation of an authorizing statute.[26] First, the court will look to the statute itself and determine whether Congress has directly spoken to the question at issue. If it has so spoken and the intent of Congress is clear, both the court and the agency must give effect to the expressed intent of Congress. In instances where congressional intent is not clear and the statutory language is ambiguous, the courts will likely defer to any reasonable agency interpretation, even if another interpretation is more plausible. Generally, as long as the agency stays within Congress's delegation of authority, it is free to make policy choices in interpreting a statute, and such interpretations are entitled to deference.[27] Here, it must be demonstrated that APHIS's "use" and "distribution" restrictions are within the bounds of Congress's delegated authority in the VSTA.

The extensive reach of APHIS's authority seems to stem from the VSTA's broad grant of authority to the USDA to "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 biological product in order to carry out the VSTA. The VSTA also provides APHIS with broad authority to "issue, suspend, and revoke licenses for the maintenance of establishments . . ." that "prepare" biological

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[24] After discussions with Creekstone, however, it appears private laboratories may need to become a "laboratory approved by State and Federal animal health officials" as per Notice 04-08. It is still unclear, nonetheless, the exact procedure for obtaining this type of approval.

[25] *See generally* Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). A reviewing court's inquiry under *Chevron* is rooted in statutory analysis and focuses on discerning the boundaries of Congress' delegation of authority to the agency. It should be mentioned that the Supreme Court recently revisited *Chevron* in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), declaring that the Food & Drug Administration lacks jurisdictional authority to regulate tobacco products. In reaching this determination, the Court discussed the first prong of *Chevron*, declaring that the proper analysis is to focus not only on the statutory clause, but, rather, to consider the structure, function, and history of all relevant provisions, interpreting a statute "as a symmetrical and coherent regulatory scheme." *Id*. at 1294. Upon concluding that Congress "squarely rejected proposals to give the FDA jurisdiction over tobacco," the Court stated that it was "obliged to defer not to the agency's expansive construction of the statute, but to Congress' consistent judgment to deny the FDA this power." *Id*. at 1315.

[26] *Id*.

[27] Arent v. Shalala, 70 F.3d 610, 615 (D.C. Cir 1995), *citing Chevron*, 467 U.S. at 843-45, 865-66.

products intended for use in the treatment of animals. Creating a regulatory and licensing scheme governing the safety, efficacy, purity, and potency of biological products seems to be well within this broad congressionally delegated authority. The VSTA and its legislative history do not appear to explicitly address who may "use" a biological product, the extent to which APHIS can deny a license, or the type of restrictions that can be placed on the licenses. Indeed, with only ten short provisions, it could be argued that Congress intended that the VSTA be implemented through a comprehensive regulatory scheme.

The USDA regulates the use and distribution of a biological product in 9 C.F.R. §102.5(d)—a provision pertaining to the Biological Product License. It states:

> Where the Administrator determines that the protection of domestic animals or the public health, interest, or safety, or both, necessitates restrictions on the use of a product, the product shall be subject to such additional restrictions as are prescribed on the license. Such restrictions may include, but are not limited to, limits on the distribution of the product or provisions that the biological product is restricted to use by veterinarians, or under the supervision of veterinarians, or both.

On March 17, 2004, the USDA, through APHIS's Veterinary Services, issued Notice No. 04-08 and invoked this purported power. It placed use and distribution restrictions on Veterinary Biological Product Licenses and Importation Permits for diagnostic test kits (including rapid tests) intended as an aid in the diagnosis of BSE. According to the Notice, such diagnostic test kits can only be sold and used by laboratories approved by State and Federal (USDA) animal health officials. Moreover, it requires that potency testing, distribution, and use of the BSE test kits be under the supervision or control of APHIS's Veterinary Services.

In light of the lack of explicit language on "use" restrictions in the VSTA, we discuss arguments that would seem to suggest that §102.5(d) is supported by the VSTA and congressional intent, as well as arguments against such support.

Arguments for the Inclusion. The USDA asserts that the VSTA provides the authority for the Department to ensure that veterinary diagnostic test kits are safe and accurate.[28] Although the legislative history for the VSTA has been recognized as "extremely sparse" by some courts,[29] the authority for APHIS to regulate the design, manufacture, importation, distribution, selling, testing, and labeling of biological products still appears broad. The authority in the VSTA to issue licenses and implement regulations for such things as the "sale," "exchange," and "shipment" of biologics could arguably capture a restriction on "use" or "distribution." Indeed, a restriction on the "sale" of the rapid test kits is exactly what APHIS has done with

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[28] Scott Kilman, *USDA Prohibits Mad-Cow Tests by Outside Labs, Causing Outcry*, WALL STREET JOURNAL, March 10, 2004, at A-1. Arguably, the "accuracy" of these test kits can only be assessed in the context of the purpose for which a diagnostic test is being used. Thus, a test that might serve as a "surveillance" tool may be insufficiently accurate to assure a farmer that all animals that test negative are free of BSE.

[29] *See, e.g.*, Animal Health Institute v. U.S. Dep't of Agriculture, 487 F. Supp. 376, 378 (D. Co 1980).

Notice No. 04-08. By placing a "sale" restriction on the license for test kits, APHIS is also apparently controlling who can use such test kits (although the regulations allow a restriction on use) and acting within its authority to issue regulations and licenses.

Every regulated biological product prepared by a licensed establishment must have a Biological Product License for the products it intends to prepare. USDA has reportedly licensed the BSE rapid test kits for only "surveillance" purposes and as mentioned above, restricts the sale and use of such kits to only those laboratories approved by State and Federal (USDA) animal health officials. Arguably, using rapid test kits for purposes other than surveillance purposes (i.e., a food safety or a marketing reason) may provide results outside the federally-accepted performance parameters for the test. For example, APHIS could argue that the tests which it approved for BSE surveillance were not evaluated to determine if they were reliable enough to support a claim that every individual animal that tests negative is actually negative.[30] Overseeing the performance of a diagnostic test kit to ensure that it produces adequate and accurate test results every time for the stated purpose may be compatible with APHIS's regulation of the purity, potency, and efficacy of a biological product.

The fact that the USDA intends to keep BSE testing within a Federal and State regulatory scheme seems consistent with the congressional recognition in 1985 that a "uniform national standard" would better serve livestock owners, veterinarians, and the American public.[31] For example, it could be quite difficult to impose a "uniform national standard" if private parties were allowed to conduct BSE testing. A private company's economic interests, for one, could significantly influence a company's compliance with federal regulatory protocol. Along the lines of maintaining a uniform standard, some courts have even determined that where safety, efficacy, purity, and potency of biological products are concerned, APHIS, through its comprehensive regulations, has preempted the field.[32] While these cases generally address the preemption of state common law tort claims, they arguably demonstrate the breadth of APHIS's oversight in the field of animal biologics. It is this expansive

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[30] With respect to the testing of Chronic Wasting Disease—the BSE analogue in deer and elk—APHIS has argued that no test can be used reliably on individual animals to determine whether that animal is free from CWD. Animal and Plant Health Inspection Service, USDA, Position Paper: *Official diagnosis of CWD should be performed exclusively by Federal and State Regulatory agency laboratories*, February 2004, available at [http://aphisweb.aphis.usda.gov/lpa/issues/cwd/positioncwdtest.doc].

[31] *See* Lynnbrook Farms v. Smithkline Beecham Corp., 79 F.3d 620 (7th Cir. 1996), *citing* S. REPT. 99-145 at 339.

[32] *See, e.g.,* Symens v. SmithKline Beecham Corp. 152 F.3d 1050 (8th Cir. 1998); Lynnbrook Farms v. Smithkline Beecham Corp., 79 F.3d 620 (7th Cir. 1996); Cooper v. United Vaccines, Inc., 117 F. Supp. 2d 864 (E. D. Wis. 2000); Brandt v. The Marshall Animal Clinic and Smithkline Beecham Corp., 540 N.W. 2d 870 (Minn. Ct. App. 1995). These cases basically hold that states are not free to impose requirements, whether through positive enactments or common law tort claims, that are different from or in addition to those requirements of the regulations that have been duly promulgated by APHIS.

field of authority that makes it plausible to argue that a regulation over the actual "use" of a rapid test kit would not be manifestly contrary to the VSTA.

The restriction on "use" and "distribution" also seems consistent with APHIS's overarching mission under the VSTA to protect U.S. public and agricultural health by assuring that biologics used in the treatment of animals are pure, safe, potent, and efficacious.[33] For instance, a rapid test kit may be "efficacious" for a program in which thousands of targeted cattle are tested to determine nationwide prevalence, but not "efficacious" to support the certification of thousands of specific, individual animals as BSE-free because the tests could have some false-negative or false-positive results. The restriction on "use" and "distribution" could also be buttressed by the USDA's objective to preserve domestic and international market confidence in U.S. agricultural commodities. For example, with respect to the testing of Chronic Wasting Disease—the BSE analogue in deer and elk—APHIS has argued that such testing must be performed exclusively by Federal and State regulatory agency laboratories in order better maintain international credibility of the U.S. animal health system.[34]

Arguments Against the Inclusion. While the VSTA and APHIS's overall mission broadly support its regulation of the "use" of a biological product, it appears the VSTA, its regulations and some legislative history place much more emphasis on the manufacture of a biological product, rather than its intended "use." For example, with respect to the VSTA regulations in subchapter E of title 9 of the C.F.R., we located only one subpart of one section (§102.5(d)), which restricts the actual "use" of a biological product (except maybe for import permits).[35] The regulatory control that APHIS is attempting to accomplish with this one subpart of the licensing regulation could be called into question when viewed comparatively to the developed legal and regulatory framework utilized by the Food and Drug Administration (FDA) and two other agencies in the Department of Health and Human Services (DHHS) to oversee similar activities.

The FDA not only regulates *human* drugs and biological products, but also participates with the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) to oversee the actual use of

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[33] The USDA specifically included a provision for "potency" testing in Notice No. 04-08 for BSE diagnostic test kits.

[34] Animal and Plant Health Inspection Service, USDA, Position Paper: *Official diagnosis of CWD should be performed exclusively by Federal and State Regulatory agency laboratories*, February 2004, available at [http://aphisweb.aphis.usda.gov/lpa/issues/cwd/positioncwdtest.doc].

[35] We did locate in 9 C.F.R. pt. 121 regulations that allow APHIS to monitor the actual possession, use, and transfer of biological agents and toxins. These regulations, however, find their authority in the Agricultural Bioterrorism Protection Act of 2002 (P.L. 107-188, Tit. II, §211) not the VSTA. They were apparently implemented in light of the increased threat of biological warfare and require the registration of any individual or entity that possesses, uses, or transfers specified agents or toxins (including BSE). It is unclear why Congress essentially had to reach outside the VSTA to support regulating the actual use and possession of these biological agents and toxins.

certain tests in laboratories through an elaborate set of certifications and accreditations.[36] The FDA is authorized to conduct these activities pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. §263a). Some may find that the regulatory control that APHIS is attempting to accomplish with §102.5(d) is similar to that of the CLIA, but uses what appears to be a much less developed legal and regulatory framework. Accordingly, there may be some doubt as to the expansiveness of the USDA's authority to implement a restriction on "use" like §102.5(d) and the extent to which Congress intended APHIS to regulate who actually "uses" a biological product.

Aside from the legislative history supporting the 1985 Amendments to the VSTA, there appears to be some support in the early legislative history and language of the VSTA that it was actually intended to regulate the *manufacture* of biological products. VSTA regulations, for example, may be promulgated to prevent the preparation and sale of worthless, contaminated, dangerous, or harmful biological products. From this language, it may be reasonable to question the extent to which the USDA can regulate the "use" of properly made and licensed biological products.[37] Moreover, during a 1914 Agriculture hearing, Dr. A. M. Farrington, Assistant Chief of the USDA's Bureau of Animal Industry, stated that with the recent production of hog cholera serums, it was "necessary to supervise the manufacture of these products so that only serums of good quality shall be produced for sale to farmers."[38] He went on to further note that the VSTA was intended to "protect the farmer and stock raiser from improperly made and prepared serums, toxins, and viruses."[39] Indeed, the abundant use of the word "prepare" (as defined in the regulations) in the VSTA and regulations would seem to reiterate Dr. Farrington's observations.

The use of the word "prepare" in licensing requirements and regulations may limit the authority of the USDA over private companies wishing to "use" rapid test kits. The regulations make clear that establishments qualified to "prepare" biological products must have a valid establishment license and at least one valid biological product license for every biologic to be "prepared" in the licensed establishment. According to APHIS regulations, "prepare" means the manufacture or production of a biological product and includes the steps and procedures used in the processing,

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[36] See [http://www.cms.hhs.gov/clia/progdesc.asp]. The CMS is charged with the implementation of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), including laboratory registration, fee collection, surveys, surveyor guidelines and training, enforcement, approvals of PT providers, accrediting organizations and exempt states. The CDC is responsible for the CLIA studies, convening the CLIA Committee, and providing scientific and technical support/consultation to DHHS/CMS. The FDA is responsible for test categorization.

[37] The USDA, however, could claim that a properly made rapid test kit used for an unlicensed purpose may be harmful and dangerous to the national herd. For example, a false positive could prompt the USDA to take drastic measures (e.g., eradication or quarantine) involving a number of cattle in order to resolve the purported problem.

[38] *Hearing before the Committee on Agriculture on the Estimates of Appropriations for the Fiscal Year Ending June 30, 1914*, (H.R. 28283) 62nd Cong. 24 (1913) (statement of Dr. A. M. Farrington, Asst. Chief Bureau of Animal Industry, Dept. of Agriculture).

[39] *Id.*

testing, packaging, labeling, and storing of a biological product. Aside from the imposition of §102.5(d) on the Biological Product License and Importation Permit, it could be argued that a private company wishing to "use" a rapid test kit would be bound only to the extent it can be shown that it is actually selling, bartering, exchanging, shipping or more broadly, "preparing" a regulated rapid test kit.[40] Here however, except for perhaps storing the rapid test kits, it may be difficult to demonstrate that a private company is actually "preparing" a biological product as contemplated by the regulations.

Summary. The USDA appears to have broad regulatory authority when it comes to the purity, safety, potency, and efficacy of biological products or more generally, their preparation, manufacture, and sale. Indeed, the overall mission of APHIS, the VSTA and its legislative history, and some case law all could be argued to support the USDA's extensive authority over the production of biological products and could be more broadly interpreted to support USDA's oversight over the actual "use" of the rapid test kits. In the alternative, given that the VSTA and its legislative history do not appear to explicitly address restrictions on the actual "use" or "distribution" of a biological product, a court might find that the VSTA is ambiguous and could give deference to a reasonable APHIS interpretation.[41] Accordingly, a valid argument could be made that the "use" and "distribution" restrictions on BSE rapid test kits are apparently within the bounds of Congress's broad delegations of authority upon the USDA to issue licenses and promulgate regulations.

Nonetheless, the arguments discussed above also seem to suggest that APHIS may not have the proper legal framework in place to support its restrictions on the "use" and "distribution" of biological products. In addition, it could be argued that the main thrust of the VSTA and its regulations still appears more applicable to the preparation, manufacture, and production of biological products rather than restricting their actual "use." However, if it can be shown that the VSTA does not explicitly make clear Congress' intention with respect to restrictions on "use" and "distribution," (i.e., the statute is ambiguous) these arguments may not withstand the deference usually accorded an agency's reasonable interpretation of the authorizing statute.

The Creekstone Decision

Assuming APHIS does have the authority to regulate who actually uses the rapid test kits, the next inquiry a reviewing court is likely to address is whether the agency's discharge of that authority was reasonable. Such a question falls within the province of traditional "arbitrary and capricious review" under 5 U.S.C.

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[40] As previously discussed, anyone who imports a biological product must hold a valid USDA permit. By requiring a permit, USDA is arguably restricting the "use" of the biological product.

[41] To determine if §102.5(d) is reasonable a court is likely to apply traditional "arbitrary and capricious review" under 5 U.S.C. §706(2)(A) (See the analysis under the Creekstone Decision section of the memo for a discussion on "arbitrary and capricious review.") We assume for purposes of this analysis that a court would find §102.5(d) reasonable, provided a court also finds that the USDA was acting within its congressionally delegated bounds.

§706(2)(A).[42] Generally, the scope of review under the arbitrary and capricious standard is narrow, and a court is unlikely to substitute its judgment for that of an agency.[43] Nonetheless, an agency must articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made. Normally, an agency rule would be arbitrary and capricious if the agency (1) has relied on factors which Congress has not intended it to consider, (2) entirely failed to consider an important aspect of the problem, (3) offered an explanation for its decision that runs counter to the evidence before the agency, or (4) is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[44]

With respect to the Creekstone case, a reviewing court would likely attempt to determine whether APHIS's decision to deny Creekstone a license to privately test for BSE was arbitrary and capricious in light of the evidence presented and congressional intent. Although we could not confirm exactly which license Creekstone applied for pursuant to federal regulations, we believe Creekstone was attempting to become a "laboratory approved by State and Federal animal health officials" as per Notice 04-08.[45] As mentioned above, courts generally provide an agency implementing an authorized regulation a considerable amount of deference; thus, it may be difficult for Creekstone to overcome APHIS's denial, provided it was based on a rational and satisfactory explanation. Aside from a brief press release on April 9, 2004 that articulates its general rationale for the denial, the USDA has not made public any detailed explanation. Accordingly, we only provide a brief analysis on conclusions that can be drawn from this press release and other supporting data.

APHIS seems primarily concerned with the implied consumer safety aspect that 100% testing may produce. It has determined, based on the findings of an international panel of experts, that there is no scientific justification for 100% testing because the disease does not appear in younger animals.[46] APHIS also seems concerned with the implied safety aspect since it believes that no test has been shown to be reliable enough to support use as a food safety test.[47] It has also claimed that

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[42] *See* Motor Vehicle Mfg. Ass'n v. State Farm Mutual Automobile Ins. Co., 463 U.S. 26 (1983).

[43] *Id*. at 43.

[44] *Id.*

[45] Telephone discussion with Mr. Bill Fielding, C.O.O., Creekstone Farms Premium Beef (May 5, 2004); Telephone discussion with Mr. James Wilson, Quality Control Manager, Creekstone Farms Premium Beef (May 6, 2004). According to Creekstone, it was seeking guidance from the USDA as to which permit or license was necessary for it to conduct BSE rapid tests. USDA apparently did not address which specific license or permit was required, but rather more broadly rejected Creekstone's request all together.

[46] USDA Statement by Bill Hawks, Undersecretary for Marketing and Regulatory Programs Regarding a Request by Creekstone for Private BSE Testing, Release No. 0141.04 (April 9, 2004).

[47] Animal and Plant Health Inspection Service, USDA, Position Paper: *Official diagnosis of CWD should be performed exclusively by Federal and State Regulatory agency* (continued...)

the chances of a "false positive" for BSE could have "devastating" effects on the U.S. economy and international trade.[48] For example, during the USDA's increase in BSE testing, early reports of two "inconclusives" (i.e., USDA parlance for a rapid test that is not negative for BSE) apparently had a negative impact on cattle markets and consumer confidence.[49] Relatedly, for the testing of Chronic Wasting Disease—the BSE analogue in deer and elk—APHIS has argued that such testing must be performed exclusively by Federal and State regulatory agency laboratories. It buttressed its decision with the claim that the international credibility of the U.S. animal health system was largely predicated on having an established set of government labs.[50]

It would appear that arguments centered around APHIS's role in providing a safe and reliable food supply both domestically and internationally are consistent with APHIS's and the USDA's overall mission and expertise. The main thrusts of the arguments may be centered around the scientific evidence that purportedly supports USDA's position. APHIS should be wary of evidence, however, that demonstrates that its decision was counter to the evidence or did not consider an important aspect of the problem. For example, APHIS has consistently argued that the testing of all animals is not scientifically justified. However, in 2002 and 2003, the USDA reportedly tested over 2,000 head of cattle younger than 30-months old for BSE.[51] There has also been some reported cases of cattle under the age of 30 months testing positive for BSE in Europe and Japan.[52] Creekstone has argued that the testing of younger animals would actually provide a useful negotiating advantage with foreign countries like Japan by disproving the theory that it is necessary to test all animals.[53] Evidence could also be introduced showing the extent to which APHIS even considered alternatives or the need for business innovation to keep up with consumer demand.

Creekstone may also try to demonstrate that its "marketing" BSE test program enhances the "surveillance" aspect of the USDA's program and does not have

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[47] (...continued)
laboratories, February 2004, available at [http://aphisweb.aphis.usda.gov/lpa/issues/cwd/positioncwdtest.doc].

[48] *Id.*

[49] *See* CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*, at 8.

[50] USDA Position Paper, *supra* note 47.

[51] Steve Mitchell, *Records contradict USDA's mad cow decision*, UNITED PRESS INTERNATIONAL, Apr. 21, 2004, available at [http://www.upi.com/view.cfm?StoryID=20040420-052613-8197r]. This report was based on a UPI FOIA request.

[52] *Id.* Others, however, believe that the number of cattle under 30 months that test positive for BSE is "statistically insignificant," and that the two cases in Japan have question marks as to whether they really were positives because both tested positive with rapid tests but negative with the more sensitive IHC test. *Testing Debate Misses the Point*, CATTLE BUYERS WEEKLY (Apr. 26, 2004).

[53] Carole Sugarman, *Creekstone completing BSE testing lab despite lack of USDA approval*, FOOD CHEMICAL NEWS, Vol. 46, No. 7 (March 29, 2004).

"implied consumer safety aspects." For example, depending on the scientific evidence presented, it may be plausible to argue that the testing of animals under a "marketing" program does not necessarily entail "treatment" as USDA regulations contemplate or require the same level of scrutiny. Also, with respect to marketing, the USDA apparently certifies many food items for quality assurances that arguably may have little to do with food safety (e.g., National Organic Program, Meat Grading and Certification, Beef Export Verification Program, and the Non-Hormone Treated Cattle Program).

Summary. With the multitude of factors that may affect this case, it is difficult to predict all the possible resolutions. Creekstone, for example, has cited a number of legal remedies that it may seek, including the approval of a "BSE tested" label, the approval of Kansas State University as an official USDA lab, and an increase in the total number of head tested under the USDA's program. Nonetheless, courts are generally unwilling to substitute their judgment for that of an agency, and a government agency generally only has to show a rational connection to the evidence. As such, provided APHIS can demonstrate that each of its reasons for keeping BSE testing within the exclusive purview of Federal and State laboratories is rationally justified by explanatory material, it appears reasonable to infer that a court would uphold APHIS's decision.