United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 9, 2008 Decided August 29, 2008

No. 07-5173

CREEKSTONE FARMS PREMIUM BEEF, L.L.C.,
APPELLEE/CROSS-APPELLANT

v.

DEPARTMENT OF AGRICULTURE AND EDWARD T. SCHAFER,
SECRETARY OF AGRICULTURE,
APPELLANTS/CROSS-APPELLEES

Consolidated with NO. 07-5199

Appeals from the United States District Court
for the District of Columbia
(No. 06cv00544)

Eric Fleisig-Greene, Attorney, United States Department of Justice, argued the cause for the appellants/cross-appellees. *Jeffrey S. Bucholtz,* Acting Assistant Attorney General, *Jeffrey A. Taylor*, United States Attorney, and *Mark B. Stern* and *Michael S. Raab,* Attorneys, United States Department of Justice, were on brief. *James J. Gilligan,* Attorney, United States Department of Justice, and *R. Craig Lawrence,* Assistant United States Attorney, entered appearances.

Russell S. Frye argued the cause for the appellee/cross-appellant. *Peter C. Choharis* entered an appearance.

Before: SENTELLE, *Chief Judge*, HENDERSON and ROGERS, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* HENDERSON.

Concurring opinion filed by *Circuit Judge* ROGERS.

Dissenting opinion filed by *Chief Judge* SENTELLE.

KAREN LECRAFT HENDERSON, *Circuit Judge*: Creekstone Farms Premium Beef, LLC (Creekstone) raises and slaughters for sale Black Angus cattle. In December 2003, many countries began to ban or severely limit importation of U.S. beef because bovine spongiform encephalopathy (BSE)—"mad cow disease"—had been found in one cow in Washington State. *See* U.S. Dep't of Agric., Publ'n No. LDP-M-143-01, An Economic Chronology of Bovine Spongiform Encephalopathy in North America 4 (2006) (Economic Chronology). To counter the fears of beef importers as well as domestic consumers, Creekstone developed a plan to test for BSE each of the approximately 300,000 cattle it slaughters each year. Declaration of John D. Stewart ¶ 6 (July 13, 2006) (Stewart Decl.). The United States Department of Agriculture (USDA), however, asserting authority under the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-59 (VSTA or Act), denied Creekstone's request to purchase or use a BSE test kit. Creekstone challenged the USDA's action in the district court, alleging that two of USDA's regulations are *ultra vires* under VSTA and that, even assuming the regulations are valid, they do not authorize USDA's restriction on the sale/use of the BSE test kit. Creekstone also challenged USDA's interpretation of another regulation. Both parties moved for summary judgment and the district court granted partial summary judgment to each party. 517 F. Supp. 2d 8, 13-16 (D.D.C. 2007). For the reasons explained below, we affirm in part and reverse in part.

I.

A. Statutory/Regulatory Background

The Congress enacted VSTA in 1913 following reports that farmers were being sold ineffective anti-hog cholera serum. *See* Agriculture Appropriation Bill: Hearings Before the Senate Comm. on Agric., 62d Cong. 23-24 (1913) (testimony of A.M. Farrington, Asst. Chief, Bureau of Animal Indus., USDA). The Act makes it "unlawful . . . to prepare, sell, barter, or exchange . . . or to ship or deliver for shipment . . . any worthless, contaminated, dangerous, or harmful virus, serum, toxin, *or analogous product* intended for use in the treatment of domestic animals." 21 U.S.C. § 151 (emphasis added). To this end, VSTA requires that "any virus, serum, toxin, *or analogous product* manufactured within the United States and intended for use in the treatment of domestic animals . . . [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" (Secretary). *Id.* (emphasis added). In addition, VSTA makes it illegal to import "any virus, serum, toxin, or analogous product for use in the treatment of domestic animals" without a permit from the Secretary. *Id*. § 152. To implement the Act, the Secretary is authorized "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 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]." *Id*. § 154 (emphasis added).[1]

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[1]Any violation of VSTA is a misdemeanor "punish[able] by a fine of not exceeding $1,000 or by imprisonment not

USDA has promulgated several regulations implementing VSTA. One regulation under review provides that "[w]here 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, the product shall be subject to . . . restrictions as . . . prescribed on the license." 9 C.F.R. § 102.5(d).[2] The second regulation under review provides that "[n]o biological product shall be brought into the United States unless a permit has been issued for such product" by the APHIS Administrator. 9 C.F.R. § 104.1(a). "Biological products" include "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." 9 C.F.R. § 101.2 (emphasis added). "Analogous products" are defined, in relevant part, as "[s]ubstances . . . which are intended for use in the treatment of animals through the detection or measurement of antigens, *antibodies*, nucleic acids, or immunity." *Id.* § 101.2(2)(ii) (emphasis added). "Treatment" is defined as the "prevention, *diagnosis*, management, or cure of diseases of animals." *Id.* § 101.2(3) (emphasis added).

B. Bovine Spongiform Encephalopathy

BSE is an invariably fatal neurological disease that causes

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exceeding one year, or by both such fine and imprisonment." 21 U.S.C. § 158.

[2]The APHIS Administrator issues the relevant license, namely a U.S. veterinary biological product license. 9 C.F.R. § 102.5(a).

degeneration of the cow's central nervous system. *See* Bovine Spongiform Encephalopathy, 70 Fed. Reg. 460, 461 (Jan. 4, 2005). BSE is believed to be caused by a type of protein called a "prion." Declaration of Lisa A. Ferguson ¶ 3 (Sept. 20, 2006) (Ferguson Decl.). Prions exist naturally in the nerve cells of many animals and are believed to help maintain normal cell function; however, the protein also exists in an abnormal form which causes BSE. Stanley B. Prusiner, *Detecting Mad Cow Disease*, Scientific American, July 2004, at 86 (Creekstone Mot. Summ. J. Ex. 3) (CX-3). BSE occurs when healthy cattle are fed the remains of an animal (ruminant) infected with abnormally formed prions. Ferguson Decl. ¶ 3. As abnormal prions accumulate within the brain cells, they cause the cells to rupture, resulting in a loss of coordination and ultimately the death of the animal. *See* CX-3, at 88; Ferguson Decl. ¶ 5. Prions that cause BSE in cattle can cause a similar disease in humans known as variant Cruetzfeldt-Jakob Disease (vCJD). Ferguson Decl. ¶ 7. Since 1986, approximately 190 people—95% of whom resided in the United Kingdom—have died as a result of confirmed cases of vCJD. *Id.* It is believed that humans can contract vCJD by consuming BSE-contaminated beef or beef products. *Id*.

BSE was first diagnosed in the United Kingdom in 1986. *Id*. ¶ 4. Since then, more than 189,000 confirmed cases of BSE in cattle worldwide have been reported. *Id.* While almost all of the cases (95%) have occurred in the United Kingdom, BSE has been found in cattle raised in at least twenty-five other countries. *Id.* In 1989, USDA banned the importation of ruminant products from countries with known BSE-infected cattle. *See* 9 C.F.R. §§ 93.401, 94.18; Ferguson Decl. ¶ 8. In 1990, APHIS began a surveillance program to determine the existence *vel non* of BSE in the nation's cattle and to evaluate the effectiveness of its import restriction in preventing the spread of the disease.

Ferguson Decl. ¶ 9. In 1997, the United States Food and Drug Administration (FDA) banned the use of all ruminant feed for cattle. *See* Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, 62 Fed. Reg. 30,936, 30,976 (June 5, 1997) (codified at 21 C.F.R. § 589.2000). Despite these efforts, however, three BSE-infected cows have been found in the United States. The first was reported in December 2003 in a Canadian-born cow in Washington State. Economic Chronology 4. In June 2004 APHIS initiated a 26-month "enhanced BSE surveillance program" under which APHIS tested over 750,000 cattle for BSE. Ferguson Decl. ¶ 9; 517 F. Supp. 2d at 10. Two more BSE-infected cattle were found—one in Texas in June 2005 and one in Alabama in March 2006. Economic Chronology 5. In July 2006, USDA announced that in light of "the extremely low prevalence of the disease in the U.S.," it intended to reduce the number of cattle tested to approximately 40,000 per year—approximately 1% of the total number of cattle slaughtered in the United States. USDA Press Release No. 0255.06 (July 20, 2006); Declaration of Paul W. Brown ¶ 15 (Oct. 27, 2006).

There are several types of BSE tests available; the most common—and the one at issue here—is the immunoassay, or "rapid," BSE test.[3] *See* CX-3, at 89-91. The rapid BSE test,

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[3]The rapid BSE test is so named because it can produce results in approximately eight hours. Other methods of testing (for example, the immunohistochemistry and bioassay methods) can take up to seven days or 36 months, respectively, to produce results. CX-3, at 90. With the rapid BSE test, tissue is harvested from the carcass's brain and treated with an enzyme which removes normally formed prions. *Id.* at 89. The sample

however, has limitations. It can detect abnormal prions only if they exist in a relatively high concentration, *id.* at 91, and abnormal prions typically reach detectable concentrations only two to three months before an animal exhibits observable symptoms. *See* Declaration of Byron Rippke ¶ 9 (Sept. 12, 2006). The incubation period for BSE (i.e., from infection to observable symptoms) is two to eight years—the average being five years—and cattle younger than thirty months are rarely symptomatic. Ferguson Decl. ¶ 5. Because most cattle for slaughter in the United States go to market before they are twenty-four months old, it is unlikely that the rapid BSE test will detect the disease. *Id.* In light of the rapid BSE test's limited efficacy, USDA believes that the routine use of the test on "clinically normal young cattle is not practical[], offers no food safety value," is "likely [to] produce false negative results" and is "meaningful and reliable . . . when used for surveillance purposes on . . . animals exhibiting some type of clinical abnormality that could be consistent with BSE" (e.g., cattle that cannot stand or walk, show signs of neurological disorders or die from an unknown cause). Ferguson Decl. ¶ 6.

Following the discovery of the first BSE-infected cow in Washington State, several major beef importing countries, including Japan, South Korea and Mexico (at the time three of the four largest importers), banned the importation of U.S. beef. Economic Chronology 4. Some countries have since resumed importing U.S. beef; however, Japan and South Korea have done so only intermittently and subject to restrictions. *See*

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is then treated with an antibody that binds to any abnormal prion. *Id.* By measuring the amount of any antibody that binds, the presence of BSE can be determined in a matter of hours. *See id.* at 90.

Supplemental Declaration of John D. Stewart ¶ 5 (Oct. 31, 2006).

C. Creekstone's Response to Market Loss

Creekstone claims to have suffered $200,000 per day in lost revenue as a result of the diminished export market. Stewart Decl. ¶ 17. Moreover, in markets where U.S. beef is available, Creekstone contends that consumer fears about BSE have diminished its sales. *See Id*. ¶¶ 4, 5 (discussing market surveys in Japan and U.S.). To allay the concerns of consumers and importers, in 2004 Creekstone made a "business decision" to perform the rapid BSE test on each cow it slaughters. Compl. ¶ 20. Creekstone sought to purchase rapid BSE test kits from Bio-Rad Laboratories, Inc. (Bio-Rad).[4] Bio-Rad informed Creekstone, however, that it could not sell Creekstone the kits without USDA authorization. On February 19, 2004, and in several later communications, Creekstone requested USDA permission to purchase the test kits. *Id*. ¶ 21. USDA denied Creekstone's requests. On March 17, 2004, USDA's Center for Veterinary Biologics issued Notice No. 04-08, ordering that the "[s]ale and use" of all BSE test kits be restricted to USDA-approved laboratories only. *See* USDA, Ctr. For Veterinary Biologics Notice No. 04-08 (Mar. 17, 2004). The Notice also declared that the "distribution and use" of all BSE test kits was to be under the "supervision or control of USDA." *Id.*[5]

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[4]Bio-Rad, a California corporation, manufactures rapid BSE test kits in France and imports them into this country under a USDA permit. *See* United States Veterinary Biological Product Permit No. 624, Bio-Rad Laboratories (Mar. 4, 2005).

[5]The USDA issued the Notice under 9 C.F.R. §§ 102.5(d) and 104.1.

Accordingly, Bio-Rad's import permit authorizes it to sell BSE test kits to USDA-approved laboratories only. U.S. Veterinary Prod. Permit No. 624, Bio-Rad Labs., at 2 (Mar. 4, 2005). USDA memorialized its decision to deny Creekstone permission to purchase rapid BSE test kits from Bio-Rad in a June 1, 2004 letter, concluding 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 international confidence in U.S. cattle and beef products." Letter from Bill Hawkes, USDA, to John D. Stewart, Creekstone Farms (June 1, 2004).[6]

On March 23, 2006, Creekstone filed a three-count complaint in the district court. Count I claimed, *inter alia*, that because VSTA "provides no authorization at all for restrictions on the *use* of products," USDA's regulation purporting to regulate the use of biological products is *ultra vires*. Compl. ¶ 32 (emphasis added). Count I also claimed that USDA's definition of "treatment" contained in regulation section 101.2 goes "beyond the scope of the rulemaking authority granted to USDA in the VSTA." *Id.* ¶ 31. Count II challenged USDA's regulation of BSE testing because it "[is] not used in the

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[6]At the suggestion of a USDA official, Creekstone subsequently asked USDA to allow Kansas State University (KSU) to designate Creekstone's Arkansas City, Kansas facility as a satellite laboratory for KSU's USDA-authorized BSE testing program. USDA rejected the request, explaining that "BSE testing is an inherently governmental function that must be conducted by Federal and State laboratories." Letter from Randall L. Levings, USDA, to Ralph Richardson, Kansas State University (Aug. 5, 2004).

treatment of domestic animals and do[es] not 'act primarily through the direct stimulation, supplementation, enhancement or modulation of the immune system or immune response,' as required by 9 C.F.R. § 101.2." Compl. ¶ 40. Finally, Count III alleged that USDA's denial of Creekstone's request to perform BSE testing is arbitrary and capricious in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). Compl. ¶¶ 42-51.

The parties filed cross-motions for summary judgment on Counts I and II of Creekstone's complaint. On March 29, 2007, the district court granted summary judgment to USDA on Count I and to Creekstone on Count II. The court first rejected Creekstone's argument that USDA lacked the authority to regulate the "use" of products under section 154 of the Act. 517 F. Supp. 2d at 13 ("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 court also upheld USDA's broad interpretation of "treatment" in sections 151-155 of the Act. *Id.* at 15-16. On Count II, however, the court concluded that USDA cannot regulate BSE testing because it cannot be used in the treatment of domestic animals. *Id.* at 16. The court reasoned that, because there is no known cure for BSE and 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). *Id.* at 16. Neither party moved for summary judgment on Count III. *See* 517 F. Supp. 2d at 12 n.5.[7] Both

[7]In district court USDA challenged Creekstone's standing and also asserted a mootness defense based on "Japan's decision in July 2006 to resume imports of U.S. beef." 517 F. Supp. 2d at 12. USDA has pursued neither argument on appeal.

parties timely appealed.

II.

We review de novo the district court's grant of summary judgment. *Nat'l Mining Ass'n v. Kempthorne*, 512 F.3d 702, 707 (D.C. Cir. 2008). We affirm a grant of summary judgment only if "there is no genuine issue as to any material fact and . . . the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In making this determination, we view the material facts in the light most favorable to the non-moving party. *Johnson v. District of Columbia*, 528 F.3d 969, 973 (D.C. Cir. 2008) (citing *Saucier v. Katz*, 533 U.S. 194, 201 (2001)).

A. Count I

1. USDA's "use" regulations[8]

We first address the question whether USDA can regulate the use of biological products under VSTA. VSTA authorizes USDA to promulgate regulations under two circumstances set forth in 21 U.S.C. § 154. First, section 154 authorizes USDA to promulgate "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." 21 U.S.C. § 154. This language authorizes regulations directed at discrete activities—preparation, sale, barter, exchange and shipment—and discrete products—viruses,

[8]We use the term "use" regulations to refer to 9 C.F.R. §§ 102.5(d) and 104.1.

serums, toxins or analogous products.[9] But this language is also limited to products that are "worthless, contaminated, dangerous, or harmful" and plainly the rapid BSE test kit cannot be so described. Section 154 further provides that USDA may promulgate "such rules and regulations as may be necessary . . . otherwise to carry out this chapter." *Id.* USDA contends that under *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), this broad language authorizes it to regulate the use of biological products. We conclude instead that the applicable standard of review is that set out in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

Ordinarily, we review an agency's interpretation of a statute that it administers under *Chevron.* We first ask "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If so, "that is the end of the matter" and we "must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. However, if "the statute is silent or ambiguous with respect to the specific issue," we move to the second step and must defer to the agency's interpretation as long as it is "based on a permissible construction of the statute." *Id.* at 843. In this case, however, we agree with Creekstone that *Chevron* does not apply to the "otherwise to carry out" language because that language was not added to the statute until 1985, *see* Food Security Act of 1985, Pub. L. No. 99-198, § 1768(b), 99 Stat. 1354, 1654 (1985)—almost ten years after USDA promulgated the predecessor of section 102.5(d). *See* Deletion of Special Licenses, 41 Fed. Reg. 44,358, 44,359 (Oct. 8, 1976). USDA

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[9]Section 154 applies to both imported products and to products manufactured in the United States. *See* 121 U.S.C. § 151 (U.S.-manufactured products); *id.* § 152 (imported products).

may not reasonably rely on statutory language that did not exist when it first adopted its regulation. *See Pub. Citizen, Inc. v. U.S. Dep't of Health & Human Servs.*, 332 F.3d 654, 659 (D.C. Cir. 2003) (applying *Skidmore* deference to regulation promulgated before amendment of statute). As the district court correctly noted, however, even without *Chevron* deference, USDA's "use" regulations nonetheless "remain[] entitled to a 'degree of deference' under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)." 517 F. Supp. 2d at 14 (quoting *Pub. Citizen*, 332 F.3d at 662).

Under *Skidmore*, " '[t]he weight [accorded to an administrative judgment] in a particular case will depend upon 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.' " *United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (quoting *Skidmore*, 323 U.S. at 140) (second alteration in *Mead*); *see Am. Fed'n of Gov't Employees v. Veneman*, 284 F.3d 125, 129 (D.C. Cir. 2002) (under *Skidmore* "USDA's view . . . constitutes 'a body of experience and informed judgment' to which we may properly resort for guidance" (quoting *Skidmore*, 323 U.S. at 140)). USDA's promulgation of section 102.5(d) satisfies *Skidmore's* standard.

As previously noted, section 102.5(d) provides that, once the APHIS 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," including "limits on the *distribution* of the product." 9 C.F.R. § 102.5(d) (emphases added). We believe regulation 102.5(d), which permits restrictions on the "use" of biological products, 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. *See, e.g.*, 21 U.S.C. §§ 151 (making it illegal to "prepare, sell, barter, exchange, or ship . . . *any* virus, serum, toxin, or *analogous product* manufactured within the United States and intended *for use in the treatment of domestic animals*, unless . . . [it] shall have been prepared, under and in compliance with regulations prescribed by the Secretary") (emphases added), 152 (requiring USDA permit to import "*any* virus, serum, toxin, or *analogous product for use in the treatment of domestic animals*") (emphases added), 153 (authorizing Secretary to inspect "*all* viruses, serums, toxins, and *analogous products, for use in the treatment of domestic animals*, which are being imported or offered for importation into the United States") (emphases added), 155 (authorizing Secretary "to issue permits for the importation into the United States of viruses, serums, toxins, and *analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous or harmful*") (emphasis added); *see Fed. Express Corp. v. Holowecki*, 128 S. Ct. 1147, 1156-57 (2008) (according *Skidmore* deference to agency interpretive position that was "reasonable," "consistent with the statutory framework" and consistently applied for 5 years). Accordingly, we find section 102.5(d) is authorized and is entitled to *Skidmore* deference.

Creekstone also challenges USDA's interpretation of section 104.1. Section 104.1 provides that "[n]o biological product shall be brought into the United States unless a permit has been issued for such product" by the Administrator. *Id.* § 104.1. Although section 104.1 does not expressly provide that the Administrator can deny an import permit based on the product's intended use (in this case, sales to Creekstone), USDA so interprets the regulation. We believe USDA's interpretation of section 104.1 is not inconsistent with the regulation and

therefore entitled to deference. *See, e.g.*, *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) ("We must give substantial deference to an agency's interpretation of its own regulations . . . unless it is plainly erroneous or inconsistent with the regulation." (quotation omitted)); *Gardebring v. Jenkins*, 485 U.S. 415, 430 (1988).

We are not persuaded by Creekstone's arguments to the contrary. Creekstone first invokes the *expressio unius est exclusio alterius* canon of statutory construction to assert that the omission of "use" from VSTA's provisions precludes USDA from promulgating a "use" regulation. With a statute like VSTA, however, which contains broad language authorizing the agency to promulgate regulations necessary to "carry out" the statute, we believe the doctrine has minimal, if any, application. *See Cheney R.R. v. ICC*, 902 F.2d 66, 69 (D.C. Cir. 1990) ("Whatever its general force, we think [*expressio unius*] an especially feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved."); *Tex. Rural Legal Aid, Inc. v. Legal Servs. Corp.*, 940 F.2d 685, 694 (D.C. Cir. 1991) ("Whatever its usefulness in other circumstances . . . this canon has little force in the administrative setting."); *see also NLRB v. Beverly Enters.–Mass.*, 174 F.3d 13, 32 (1st Cir. 1999); *Ragsdale v. Wolverine World Wide, Inc.*, 535 U.S. 81, 97, 102 (2002) (O'Connor, J., dissenting) (arguing that "*expressio unius* ought to have somewhat reduced force in th[e] context" of statute authorizing agency to " 'prescribe such regulations as are necessary to carry out' the Act" (quoting 29 U.S.C. § 2654)).

Nevertheless, Creekstone argues that section 154's "otherwise to carry out" language cannot support the "use" regulations because, as previously noted, the "otherwise to carry out" language was not added to section 154 until almost ten

years after USDA first asserted the authority to regulate the "use" of biological products. As the district court correctly noted, however, the argument "cuts both ways." 517 F. Supp. 2d at 13 n.6. Because section 102.5(d) was already in effect when the Congress amended VSTA in 1985, it had the opportunity to alter the regulation but did not do so. *See Doris Day Animal League v. Veneman*, 315 F.3d 297, 300 (D.C. Cir. 2003) (" '[W]hen Congress revisits a statute giving rise to a longstanding administrative interpretation without pertinent change, the congressional failure to revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.' " (quoting *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 846 (1986) (quotation omitted))). But Creekstone asserts that the 1985 amendment does not satisfy the requirements of the legislative reenactment doctrine because the "application of the legislative reenacement doctrine requires a showing of both congressional awareness and express congressional approval of an administrative interpretation if it is to be viewed as statutorily mandated." *Gen. Am. Transp. Corp. v. ICC*, 872 F.2d 1048, 1053 (D.C. Cir. 1989) (quotation omitted). Even assuming the 1985 amendment does not satisfy the legislative reenactment doctrine, however, the Congress's 1985 decision to leave section 102.5(d) undisturbed is "persuasive evidence" that it is consistent with congressional intent. *See NLRB v. Bell Aerospace Co. Div. of Textron, Inc.*, 416 U.S. 267, 274-75 (1974) ("[A] court may accord great weight to the longstanding interpretation placed on a statute by an agency charged with its administration." (footnote omitted)).[10]

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[10]Creekstone also argues that USDA's "use" regulations should be invalidated because USDA did not claim the authority to regulate the use of biological products until 63 years after

Creekstone also argues that VSTA's legislative history demonstrates that the Congress intended to regulate manufacturers and importers of biological products, not users like Creekstone. Creekstone cites the 1913 testimony of A.M. Farrington, Assistant Chief of the Bureau of Animal Industry, before the House Committee on Agriculture, to the effect that VSTA was meant to allow USDA to regulate the preparation and marketing of biological products. *See* Agriculture Appropriation Bill: Hearings Before the Senate Comm. on Agric., 62d Cong. 23-24 (1913) (testimony of A.M. Farrington, Asst. Chief, Bureau of Animal Indus., USDA). We are not persuaded. The legislative history of VSTA is "extremely sparse," *Animal Health Inst. v. USDA*, 487 F. Supp. 376, 378 (D. Co. 1980), and the history that does exist does not conclusively support either interpretation. *See, e.g.*, S. Rep. No. 62-1288, at 2 (1913) (VSTA is intended "to control[] *use*[] by preventing the interstate shipment[] of dangerous drugs." (emphasis added)). In any event, whether a "use" regulation was contemplated by the Congress in 1913, we believe the Congress subsequently endorsed the same in 1985.

Finally, Creekstone argues that the Agricultural

VSTA was enacted. We do not agree. "To be sure, agency interpretations that are of long standing come before us with a certain credential of reasonableness, since it is rare that error would long persist. But neither antiquity nor contemporaneity with the statute is a condition of validity." *Smiley v. Citibank*, 517 U.S. 735, 740 (1996) (sustaining Comptroller of the Currency's 1996 regulation promulgated more than 130 years after governing statute—National Bank Act of 1864—was enacted).

Bioterrorism Protection Act of 2002 (ABPA)[11] supports its claim that VSTA does not authorize a "use" regulation. ABPA gives the Secretary authority to regulate "each biological agent and each toxin that [he] determines has the potential to pose a severe threat to animal or plant health." 7 U.S.C. § 8401(a)(1)(A). The House Conference Report accompanying ABPA noted that the legislation was needed, in part, because of "the inadequacy of the penalty provisions of [VSTA]—enacted in 1913 and under which USDA currently regulates these dangerous agents—as well as the lack of authority for the Secretary of Agriculture to regulate *possession* of biological agents and toxins that pose a severe threat to plant or animal health." H.R. Rep. No. 107-481, at 124 (2002) (Conf. Rep.) (emphasis added). According to Creekstone, the Report shows the Congress did not believe that VSTA gives USDA the authority to regulate the use of biological products. We disagree. First, ABPA governs only those substances that "pose a severe threat to plant or animal health." VSTA, by contrast, encompasses all biological products intended "for use in the treatment of domestic animals." 21 U.S.C. §§ 151, 152. Further, the Congress effectively refuted Creekstone's interpretation by specifically exempting from ABPA products already regulated under VSTA. *See* 7 U.S.C. § 8401(g)(1)(C).

2. USDA's regulation of diagnostic testing

In Count I Creekstone also argues that USDA lacks the authority to regulate diagnostic testing in general because it is not used in the "treatment" of domestic animals as treatment was

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[11]ABPA is part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, §§ 211-13, 116 Stat. 594, 647 (codified at 7 U.S.C. § 8401).

defined in 1913. *See* Compl. ¶ 31; 517 F. Supp. 2d at 12. According to Creekstone, in 1913, " 'treat' was defined, *inter alia*, as: '[t]o care for medicinally or surgically; to manage in the use of remedies or appliances; as, to treat a disease, a wound, or a patient.' " Creekstone Br. 27 (citing Webster's Revised Unabridged Dictionary (1913 ed.)). USDA's regulation, however, defines "treatment" as "the prevention, *diagnosis*, management, or cure of diseases of animals." 9 C.F.R. § 101.2 (emphasis added). We see no reason to disturb USDA's definition as set forth in section 101.2. Indeed, Creekstone acknowledges that "[t]he word 'treatment' does not have a precise meaning and is not a legal term of art." Creekstone Br. 27. And we owe USDA a considerable degree of deference in its interpretation of the term, bearing, as it does, on USDA's charge to "administer[] our federal meat and poultry inspection laws." *Am. Fed'n of Gov't Employees*, 284 F.3d at 129 (applying *Skidmore*); *see Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997) ("[W]e review scientific judgments of the agency 'not as the chemist, biologist, or statistician . . . , but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.' " (quoting *Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976))). Given the "degree of deference" we owe USDA, we uphold its definition of "treatment" as including diagnosis and therefore its authority to regulate BSE testing for the purpose of diagnosis.

B. Count II

In Count II, Creekstone challenges USDA's regulation of the rapid BSE test kit because, again, it is not used in the "treatment" of domestic animals. Compl. ¶¶ 40. The district court agreed, reasoning that "[e]ven if USDA is correct that diagnosis *in general* is an inherent and crucial aspect of treatment," USDA cannot consider BSE testing diagnostic because "[t]here is no known treatment or cure for BSE . . . and

BSE test kits are used only on animals that are dead." 517 F. Supp. 2d at 16 (citation omitted) (emphasis in original). We disagree. As already noted, section 101.2 defines "treatment" as "the prevention, diagnosis, management, *or* cure of diseases of animals." 9 C.F.R. § 101.2 (emphasis added). Thus, in order to satisfy the definition, the rapid BSE test kit need fulfill only *one* of the functions. Plainly, rapid BSE testing is used to diagnose the disease. Moreover, rapid BSE testing plays a valuable role in preventing and managing the spread of BSE. It allows 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 (e.g., the ruminant feed ban). Thus, while there is no way to "treat" or cure the dead cow if the test is positive, the test kit nonetheless plays an important diagnostic role. Accordingly, we are persuaded by USDA's reasonable reading of "diagnosis" to include rapid BSE testing.

Creekstone counters that USDA's position here is inconsistent with its earlier statements about BSE testing. It claims that USDA acknowledged in a 2005 rulemaking that BSE testing of cattle at slaughter is not "meaningful in the context of . . . animal health" and that surveillance testing for BSE "is not a [disease] mitigation measure." Importation of Whole Cuts of Boneless Beef from Japan, 70 Fed. Reg. 73,905, 73,914 (Dec. 14, 2005). The statement comes from a USDA rulemaking setting forth various conditions for importing Japanese beef into the United States. *Id.* In response to a comment urging "a mandatory [BSE] testing requirement" for all Japanese imports, USDA declared that it "d[id] not consider the testing of bovines at slaughter to be scientifically justified or meaningful in the context of either human or animal health." *Id.* USDA explained that universal testing is not "meaningful" because, given BSE's long incubation period and the relatively young age of most cattle at slaughter, it would not produce meaningful results. *Id.*

We read USDA's comment that BSE testing is "not meaningful in the context . . . of animal health" to refer only to blanket BSE testing and not to the efficacy of BSE testing when used on high-risk cattle only. We also read USDA's comment that "surveillance is not a [disease] mitigation measure" to refer only to universal testing. *See id.* (noting "[a] statistically and epidemiologically valid surveillance plan *is* crucial to monitoring the success of risk mitigation measures." (emphasis added)).[12] Indeed, USDA permits "targeted" BSE testing in approved laboratories as part of its BSE surveillance program. *See* 70 Fed. Reg. at 475 ("The purpose of a surveillance program is to gauge the level of BSE prevalence. This can be achieved through targeted sampling . . . .").

To sum up, we conclude that section 102.5(d), 9 C.F.R. § 102.5(d), which allows USDA to impose "restrictions on the use" of a biological product, including "limits on . . . distribution," is valid; that under section 104.1, 9 C.F.R. § 104.1, USDA can restrict the importation of a "biological product" by limiting its sale to certain users; that USDA's definition of "treatment" set forth in 9 C.F.R. § 101.2(3) is reasonable; and that USDA can regulate the use of the rapid BSE test kit by, *inter alia*, restricting its distribution and sale. Count III of Creekstone's complaint is not before us and therefore we do not reach it.

For the foregoing reasons, the district court's grant of summary judgment to USDA on Count I is affirmed, its grant of

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[12]Creekstone also highlights a comment from a USDA publication stating that "BSE has no cure or treatment." *See* Economic Chronology 3. USDA's observation regarding BSE contained in a document that carries no force of law does not affect USDA's authority to regulate BSE testing.

summary judgment to Creekstone on Count II is reversed and the case is remanded for further proceedings consistent with this opinion.

So ordered.

ROGERS, *Circuit Judge*, concurring: I join in affirming the grant of summary judgment to the Agriculture Department and reversing the grant of summary judgment to Creekstone Farms. However, I do so on the ground that the Department's interpretation of 9 C.F.R. § 104.1, as allowing it to restrict import permits based on intended use of a biological product, is entitled to deference, *see Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc*., 467 U.S. 837 (1984); Op. at 15; 21 U.S.C. § 152.[1] See Op. at 4, 14-15. Because the Department exercised this authority to prevent the importation of BSE test kits on behalf of Creekstone Farms, *see* Op. at 8-9 & nn.4, 6, and the Department's definition of treatment, 9 C.F.R. § 101.2(3), is reasonable, Op. at 20-21, there is no need for the court to opine on unrelated aspects of the Department's regulations implementing the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-59; *cf. Stanton v. D.C. Court of Appeals*, 127 F.3d 72, 74 (D.C. Cir. 1997).

[1] Our dissenting colleague does not address this regulation or 21 U.S.C. § 152.

SENTELLE, *Chief Judge*, *dissenting*: Though I respect my colleagues' careful analysis of the application of the *Chevron* doctrine to the governing statutes in this case, in my view the Department of Agriculture's interpretation of those statutes does not survive *Chevron* Step 2. I will grant the existence of some ambiguity (no doubt intended by Congress) in the Virus-Serum-Toxin Act, 21 U.S.C. §§ 151-159 (2007) ("VSTA"). I think, however, that the Department exceeds the bounds of reasonableness in the interpretation assumed in its regulations. In its interpretation of the terms within the statute, as well as its understanding of the power afforded by the statute, the Department has gone as far as it could and, in my view, farther than it *reasonably* could in aggregating power to itself.

First, the VSTA covers "any . . . virus, serum, toxin, or *analogous product* . . . ." 21 U.S.C. § 151 (emphasis added). Nothing in the Department's regulations or its filings in the district court suggests an analogy between the test kits at issue and the viruses, sera, or toxins covered by the statute. Further, I find unpersuasive the Department's arguments that a product with no other use than the diagnosis of an untreatable and invariably fatal disease is a form of "treatment."

Finally, I find myself unable to join the conclusion in Judge Henderson's opinion that the language in § 154 empowering the Department of Agriculture to "otherwise . . . carry out" the goals of the statute includes the authority to regulate the "use" of biological products. While it is true that the "*expressio unius est exclusio alterius*" canon of statutory construction is applied with muted force in "the administrative setting," Maj. Op. at 15 (quoting *Texas Rural Legal Aid, Inc. v. Legal Services Corp.*, 940 F.2d 685, 694 (D.C. Cir. 1991)), the concept does not go away, even in the administrative setting. As we have often held, congressional provision of an expressed authority mandate to accomplish statutory goals "does not create for the agency 'a roving commission' to achieve those or 'any other laudable

goal,'" *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)), by means beyond the authority granted in the statute. I therefore would accept Creekstone's argument that the "otherwise to carry out" language of § 154 cannot support the "use" regulations.

In short, I would affirm the district court's grant of summary judgment on Count II and reverse its denial on Count I. I would further note that Count III of this action will return to the district court for application of the arbitrary and capricious standard. It seems that the Department's fear is that Creekstone's use of the test kits would enable it to provide buyers with a false assurance that the cattle from which its beef is obtained are free of Bovine Spongiform Encephalopathy. However, as I read the record, all Creekstone hopes to do is assure foreign buyers that the beef is as well-tested as would be the case with beef produced in the home countries of those buyers. I will be interested in learning later whether this interdiction by the Department can survive the arbitrary and capricious test that will govern the district court's review of that additional count.