PETITION BEFORE THE
UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY INSPECTION SERVICE

THE HUMANE SOCIETY OF THE UNITED STATES 2100 L St., N.W. Washington, DC 20037, **FARM SANCTUARY** P.O. Box 150 Watkins Glen, NY 14891, **MICHAEL BAUR**, 441 E. Fordham Rd. Bronx, NY 10458 *Petitioners,* **MIKE JOHANNS** Secretary, United States Department of Agriculture, 14th St. and Independence Ave., S.W. Washington, DC 20250-0100, **DR. BARBARA MASTERS**, Acting Administrator, Food Safety and Inspection Service United States Department of Agriculture, 14th St. and Independence Ave., S.W. Washington, DC 20250-0100, *Respondents,*	Docket No.

PETITION FOR RULEMAKING

I. Introduction

This petition is submitted on behalf of The Humane Society of the United States ("HSUS"), Farm Sanctuary, and Michael Baur ("petitioners") and requests action by the United States Department of Agriculture, Food Safety and Inspection Service

(collectively "USDA") regarding the slaughter of non-ambulatory ("downer") cattle. Specifically, petitioners request that the USDA finalize the interim final rule entitled "Prohibition on the Use of Specified Risk Material for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle," published at 69 Fed. Reg. 1862 (January 12, 2004).

As described in more detail below, the recent confirmation of a second case of bovine spongiform encephalopathy (BSE), or "mad cow disease," in the United States—and the fact that this case, like the last, was associated with a downed animal—conclusively demonstrates that issuance of a final rule cannot be delayed any further. As the USDA is well-aware, all six cases of BSE-positive animals in North America involved downer livestock. Additionally, at least three of the six cases involved cows thought by authorities to be unable to walk due to injury, rather than illness.

The American public has zero tolerance for BSE-infected animals in the food supply. More than 21,000 Americans submitted comments on the USDA's interim rule, and 99 percent either favored the downer policy or an expansion of its scope to include other livestock. Thus, prompt action to finalize the downer rule is of critical interest to both the American people and the nation's economy, since even a single infected animal processed for human consumption will put Americans at risk and do lasting damage to consumer confidence.

Permanently banning downed cattle from the human food supply not only protects public health and the nation's economy, but also promotes the humane treatment of farm animals. Downed animals sent to slaughter suffer immeasurably. They are often forced to walk with broken bones and other painful injuries, or when they cannot move, they are

forcibly dragged by chains or pushed by a bulldozer. A permanent ban on processing downed cattle would also provide an incentive for producers and transporters to improve handling and care of animals to make sure they do not go down in the first place.

As explained in detail below, the USDA has ample legal authority under the Federal Meat Inspection Act (FMIA), 21 U.S.C. § 601 et seq., to support the issuance of a final rule, and the required public notice and comment process under the Administrative Procedures Act (APA), 5 U.S.C. § 553(c), has already been completed. Moreover, in light of the serious threat posed by BSE, any further delay in issuance of a final rule may constitute unreasonably delayed agency action under section 555(b) of the APA. Accordingly, the Petitioners respectfully request that the USDA immediately finalize the interim rule in order to ensure that downed cattle do not enter the nation's food supply.

II. Interests of the Petitioners

Petitioner The HSUS is a non-profit charitable organization founded in 1954 that promotes the protection of all animals. It maintains its headquarters in Washington, D.C., and is the largest animal protection organization in the United States, with more than nine million members and constituents. The HSUS's mission is to foster the humane treatment of all animals through several program initiatives. The HSUS actively advocates against practices that injure or abuse farm animals and promotes the humane slaughter of animals who will enter the food chain. Furthermore, The HSUS offers information regarding the inhumane treatment of animals on a wide spectrum of topics, including the effects of intensive confinement and transport of farm animals and public health implications associated with the practice of slaughtering downers. Some HSUS members consume meat and other products that come from U.S. slaughter facilities.

These consumers have a strong personal interest in ensuring that cattle slaughtered for food are both safe for human consumption and treated in a humane and compassionate manner.

Petitioner Farm Sanctuary is a farm animal rescue and protection organization dedicated to ending the suffering of animals used for food. It is a national nonprofit corporation organized and existing under the laws of the State of Delaware with its principal place of business in Watkins Glen, New York. Farm Sanctuary also maintains and operates an office and shelter for rescued farm animals in Northern California. It was founded in 1986. Over the last 19 years, Farm Sanctuary has become the nation's largest farm animal advocacy and protection organization with more than 100,000 members. Farm Sanctuary's members have a strong personal interest in ensuring that cattle slaughtered for food are treated in a humane and compassionate manner.

Petitioner Michael Baur is an adult individual residing in Riverdale, New York. He is a regular consumer of meat products, including beef. Because Mr. Baur regularly eats beef, he is concerned about consuming adulterated meat as well as the health risks associated with meat from downed animals. Mr. Baur has a strong personal interest in ensuring that cattle slaughtered for food are both safe for human consumption and treated in a humane and compassionate manner.

III. Action Requested

Pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,[1] the Administrative Procedure Act,[2] and

[1] U.S. Const. Amend I.
[2] 5 U.S.C. § 553(e).

the USDA's implementing regulations,[3] the undersigned submit this citizen petition for rulemaking under the FMIA[4] requesting the Secretary take actions to comply with the express intent of Congress under the Act and its implementing regulations by prohibiting downed animals from entering the food chain, and thereby protect the public from consuming a product potentially contaminated with BSE prions which may cause variant Creutzfeldt-Jakob Disease (vCJD), an invariably fatal disease. In addition, petitioners request that the USDA take this action to protect public health, agriculture, and the economy, and to promote animal welfare. Specifically, petitioners request that the USDA issue a final regulation, as reflected in the interim final rule, banning the slaughter of downer cattle. See "Prohibition on the Use of Specified Risk Material for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" 69 Fed. Reg. 1862 (Jan. 12, 2004).

IV. Legal Background

A. The Federal Meat Inspection Act

Enacted in 1907, the FMIA establishes an essentially binary classification system, under which the Food Safety and Inspection Service's (FSIS's) paramount duty is to determine whether meat products are "adulterated" and to prevent "adulterated" meat products from entering the human food supply.[5] Section 601 of the FMIA broadly defines "adulterated" to apply to:

> "any carcass, part thereof, meat or meat food product…(m)(1) if it bears or contains any poisonous or deleterious substance that may render it injurious to health…(m)(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful,

[3] 7 C.F.R. § 1.28.
[4] 21 U.S.C. § 601 *et seq.*
[5] Id.

unwholesome, or otherwise unfit for human food"[6]

Sections 604 and 606 of the FMIA impose on the FSIS the duty to inspect animals capable for use as human food both before they enter a slaughtering facility and after slaughter, to ensure that no part of a carcass determined to be "adulterated" passes into the human food supply.[7] Accordingly, the FSIS is to mark carcasses which it determines to be adulterated as "Inspected and Condemned" and to mark those found to be unadulterated as "Inspected and Passed."[8] Any meat condemned "shall be destroyed for food purposes…in the presence of an inspector."[9] Additionally, the FMIA authorizes the FSIS to promulgate rules and regulations necessary to give effect to the Act.[10]

V. Factual Background

A. BSE in North America

On December 9, 2003, a four-year-old Holstein dairy cow arrived at Vern's Moses Lake Meats in Washington State, struggling with what was then believed to be calving-related paralysis. She was slaughtered, and the meat was sent to two processing plants. Less than two weeks later, on December 22, 2003, tests confirmed that the cow had been infected with BSE. The cow, originally from a farm in Alberta, Canada, was the first BSE-infected ruminant found within the United States. Two days later, on December 24, then USDA Secretary Ann Veneman announced a recall of approximately 10,000 pounds of meat from the two processing plants to prevent contaminated meat from

[6] Id. at § 601(m).
[7] Id. at §§ 603, 604, 606.
[8] Id. at §§ 604, 606, 607.
[9] Id. at § 604.
[10] Id. at § 621.

entering the human food supply.[11] After the announcement, as many as 50 countries imposed a ban on U.S. beef imports.[12] Since that time, another case of BSE has been reported and confirmed in the United States.[13]

Since 2002, cases of BSE have been confirmed in 23 countries with monitoring programs. In the European Union, more than 100,000 cases have been confirmed. Four cases have been confirmed in Canada. In the last two years, 932 cases have been confirmed, worldwide.[14]

BSE is a chronic, degenerative disease first identified in the United Kingdom in 1986. In later stages of the disease, infected cows exhibit poor coordination, difficulty in walking, changes in temperament, and weight loss. However, the infections that cause BSE can exist for several years before the disease manifests itself.[15]

Believed to be caused by a prion, an infectious protein, the disease is alarmingly threatening as, unlike conventional pathogens, prions and their infectivity cannot be

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[11] *U.S. officials plotting trail of sick cow: Import bans may be costly to American beef industry*, CNN, Dec. 24, 2003, http://www.cnn.com/2003/US/12/24/mad.cow/ (accessed April 18, 2005).

[12] *USDA's Gutsy Inspector General Deserves Gratitude From Cattle Industry, Consumers*, Nebraska State Paper.com, June 27, 2005, http://nebraska.statepaper.com/vnews/display.v/ART/2005/06/27/42c02ebef29f5 (accessed July 7, 2005).

[13] *U.S. Mad Cow Suspect Tests Positive for the Disease*, Environment News Service, June 24, 2005, http://www.ens-newswire.com/ens/jun2005/2005-06-24-06.asp (accessed July 5, 2005).

[14] World Organisation for Animal Health (OIE), *Number of reported cases of bovine spongiform encephalopathy (BSE) in farmed cattle worldwide (excluding the United Kingdom)*, (updated April 14, 2005) www.oie.int/eng/info/en_esbmonde.htm, (accessed April 17, 2005).

[15] Walker KD *et al*, *Comparison of bovine spongiform encephalopathy risk factors in the United States and Great Britain*, Journal of the American Veterinary Medical Association (1991); Marsh RF, *Bovine spongiform encephalopathy: a new disease of cattle?*, 1993 Archives of Virology 7(Suppl) (1993); Prusiner SB, *The prion diseases*, Scientific American, 48-57 (Jan. 1995).

adequately destroyed by cooking, canning, freezing, radiation, heat, formaldehyde sterilization, or domestic bleach.[16]

According to the FSIS, "[I]t is known that cattle can become infected with BSE by eating feed contaminated with the infectious BSE agent."[17] Despite the U.S. Food and Drug Administration's 1997 prohibition on the "use of most mammalian protein in the manufacture of animal feed intended for cattle and other ruminants,"[18] blood is currently exempted from the feed ban, meaning cow's blood collected at slaughter facilities can be fed to calves, pigs, and chickens.[19]

It is believed by scientific authorities, including the FSIS, the U.S. Food and Drug Administration, and the World Health Organization (WHO), that vCJD, a fatal brain disease in humans, results from consumption of BSE-contaminated products.[20] Indeed, allowing non-ambulatory animals to be processed for human consumption threatens the safety of the food supply, as they are understood to be at heightened risk for BSE. A

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[16] Taylor DM, *Bovine Spongiform Encephalopathy*, 49 Medical Laboratory Sciences 334, 334-9 (1992); Lacey RW and Dealler SF, *The BSE Time Bomb?* 21 The Ecologist; 117, 117-22 (1991); Marsh RF and Bessen RA, *Epidemiologic and Experimental Studies on Transmissible Mink Encephalophy*, 80 Developments in Biological Standardization, 111, 111-18 (1993); Dealler SF and Lacey R, *Beef and Bovine Spongiform Encephalopathy*, 7 Nutrition and Health, 117, 117-29 (1991); Dealler SF and Lacey R, *Transmissible Spongiform Encephalopathies*, 7 Food Microbiology, 253, 253-79 (1990); Holt TA and Phillips J, *Bovine Spongiform Encephalopathy*, 296 British Medical Journal, 1581, 1581-2 (1988).

[17] USDA, FSIS, *Production and Inspection, Fact Sheet*: *Bovine Spongiform Encephalopathy—'Mad Cow Disease*, www.fsis.usda.gov/Fact_Sheets/Bovine_Spongiform_Encephalopathy_Mad_Cow_Disease/index.asp; (accessed April 17, 2005).

[18] Id.

[19] Food and Drug Administration, *Animal proteins prohibited in ruminant feed*, Code of Federal Regulations, 21, C.F.R.§ 589.2000 (2005).

[20] USDA, FSIS, *Bovine Spongiform Encephalopathy—'Mad Cow Disease*,' op cit; World Health Organization (WHO), *Variant Creutzfeldt-Jakob disease*, http://www.who.int/mediacentre/factsheets/fs180/en/, (accessed April 17, 2005).

Swiss study, one of several cited by the FSIS in the interim rule, found that non-ambulatory cattle are 49 to 58 times more likely to have BSE than cattle identified through passive surveillance—those reported to veterinary authorities as BSE-suspect based on clinical observation.[21]

Although only two cases of a BSE-infected cattle have been found thus far in the United States, international experts have concluded that for each clinically affected animal identified, many others are infected or exposed, raising the very real possibility that many more BSE-positive animals could be found in this country.[22] The FSIS reports that as of December 1, 2003, "a total of 153 cases of vCJD had been reported in the world: 143 from the United Kingdom, six from France, and one each from Canada, Ireland, Italy, and the United States."[23] vCJD is incurable and leaves affected individuals with deteriorating mental faculties and muscular coordination, eventually leading to death. The WHO has recommended, "No part or product of any animal which has shown signs [of BSE] should enter any (human or animal) food chain; Countries should not permit tissues that are likely to contain the BSE agent to enter any (human or animal) food chain; All countries should ban the use of ruminant tissues in ruminant feed."[24]

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[21] Doherr MG, *et al*, *Targeted screening of high-risk cattle populations for BSE to augment mandatory reporting of clinical suspects*, 51 Preventive Veterinary Medicine (1-2):3-16 (2001); USDA, FSIS, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle," 69 Fed. Reg. 1862 (Jan. 12, 2005).

[22] Liechti R. Conference report: The international conference on bovine spongiform encephalopathy and food safety," April 17-18, 2002, Food Control15:71-7 (2004).

[23] USDA, FSIS, *Bovine Spongiform Encephalopathy—'Mad Cow Disease,'*" op cit.

[24] World Health Organization (WHO), "Variant Creutzfeldt-Jakob disease,"op cit.

According to USDA estimates, between 150,000 to 200,000 non-ambulatory disabled cattle are presented for slaughter annually.[25] The FSIS has acknowledged both that the potential infectivity of non-ambulatory disabled cattle is unknown and that the agency believes the potential for infectivity to be "significant."[26]

B. FSIS Response to 2003 BSE Diagnosis in Washington State

In response to the December 2003 discovery of a BSE-infected cow in Washington State, the FSIS published in the Federal Register an interim final rule on January 12, 2004.[27] The interim rule amends, *inter alia*, regulations codified at 9 C.F.R. §§ 309, 310, 311 concerning both "ante-mortem" and "post-mortem" inspection of cattle presented for slaughter as well as the FSIS's disposition of carcasses. The interim rule amended USDA regulations by mandating that all "non-ambulatory disabled cattle" be condemned, meaning disposed of so as to ensure that their carcasses are not processed for human consumption.[28]

The interim rule defines non-ambulatory disabled livestock and requires that FSIS inspectors condemn all non-ambulatory disabled cattle.[29] Non-ambulatory disabled livestock are defined as follows:

> "Non-ambulatory livestock are livestock that cannot rise from a recumbent position or that cannot walk, including, but not limited to, those with broken appendages, severed tendons or ligaments, nerve paralysis, fractured vertebral column, or metabolic conditions."[30]

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[25] FSIS, Preliminary Analysis of the Interim Final Rules and an Interpretive Rule To Prevent the BSE Agent From Entering the U.S. Food Supply, 30 (Apr. 7, 2004).
[26] Id., at 27-28.
[27] Prohibition of the Use of Specified Risk Materials for Human Food and Requirments for the Disposition of Non-Ambulatory Disabled Cattle, 69 Fed. Reg. 1862 (Jan. 12, 2004).
[28] 69 Fed. Reg. at 1870.
[29] 9 C.F.R. §§ 309.2(b), 309.3(e) 69 Fed. Reg. 1862, 1862, 1870.
[30] 9 C.F.R. § 309.2(b).

The FSIS accepted comments on the interim final rule between January 12, 2004 and July 1, 2004. During this period, the FSIS received 22,211 comments suggesting one or more of the following options:

1) Support of FSIS's prohibition on slaughter of non-ambulatory disabled cattle for human food;
2) Support for making the prohibition permanent;
3) Expanding the prohibition on slaughter of non-ambulatory disabled animals to other species;
4) Humanely euthanizing non-ambulatory disabled cattle; and
5) Extending the ban of the use of non-ambulatory disabled animals in animal feed or pet food.[31]

Under the interim rule, all cattle who are "nonambulatory disabled" and presented for inspection by a Veterinary Medical Officer ("VMO") and subsequent slaughter at a facility will be humanely euthanized and will not be processed for human consumption. Likewise, the interim rule provides for the humane euthanasia and removal from the human food chain of all cattle who demonstrate central nervous system ("CNS") symptoms. Thus, under the rule, any animal who is either non-ambulatory or has CNS symptoms when initially inspected ("ante-mortem inspection") is humanely euthanized and is not processed for human consumption.

In its interim rule, the FSIS provides compelling reasons to support a total ban on the processing of non-ambulatory disabled cattle for human consumption. The FSIS's interim rule makes abundantly clear that non-ambulatory animals are more likely to test positively for BSE than ambulatory animals and that "the typical clinical signs associated with BSE cannot always be observed in non-ambulatory cattle infected with BSE because the signs of BSE often cannot be differentiated from the typical clinical signs of the many

[31] See, list of all commenters, http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/Docs_03-025N.htm.

other diseases and conditions affecting non-ambulatory cattle."[32] In addition, the interim rule recognizes that a total ban on human consumption of non-ambulatory disabled cattle is preferable to allowing human consumption of these animals: "[P]ermitting the carcasses of non-ambulatory cattle to be used for human food if the animal tests negative for BSE will not provide the same level of protection against human exposure to the BSE agent that prohibiting these cattle from entering the human food supply will."[33] For these sound reasons, the interim rule proscribes processing for human consumption any non-ambulatory animals who are presented for ante-mortem inspection.

On many occasions, the FSIS has acknowledged that downed cattle are among "populations considered to be at highest risk for BSE."[34] Similarly in a report titled Preliminary Analysis of the Interim Final Rules and an Interpretive Rule to Prevent the BSE Agent From Entering the U.S. Food Supply, the FSIS states:

> "The level of infectivity associated with non-ambulatory disabled cattle that do not display CNS disorders is not known. The proportion of total potential infectivity associated with this type of non-ambulatory disabled cattle is thought to be significant….Removal of non-ambulatory cows from potential human exposure reduces the total amount of potential human infectivity."[35]

VI. The Most Recent Case of BSE in the United States

In November 2004, a USDA laboratory in Ames, Iowa, performed two tests on what appeared to be a native-born cow suspected of having BSE. [36] After the USDA's test came up largely negative, the agency announced that the animal did not have mad

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[32] 69 Fed. Reg. at 1870.
[33] Id.
[34] Dr. Ron DeHaven (Administrator, APHIS), Dr. Barbara Masters (Acting Administrator, FSIS) *Joint Statement* (May 3, 2004).
[35] FSIS, Analysis of the Interim Final Rules, 27-28 (Apr. 7 2004).
[36] USDA, APHIS, Factsheet, "Bovine Spongiform Encephalopathy (BSE) EPI Report," June 2005, http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/vs_bse_epireport%206-29-05.pdf; (accessed July 6, 2005).

cow disease.[37] Approximately seven months after the initial testing, USDA Inspector General Phyllis K. Fong recommended further tests on specimens of the same cow.[38]

At the urging of the Inspector General, a test known as the Western blot, which is widely used in England and Japan but not in the United States, came up positive.[39] Because this test differed from results of the tests in November 2004, a specimen from the same animal was sent to a laboratory in Weybridge, England, that is considered pre-eminent in its field. Several tests were conducted there, and all of them came up positive.[40]

Late in the afternoon on Friday, June 24, 2005—more than seven months after the initial test suggesting the presence of BSE—the USDA announced the latest mad cow case in the United States had been confirmed.[41] The USDA subsequently traced the infected cow to a herd in Texas.[42] This latest case is the first confirmation of a U.S.-born cow testing positive for BSE.[43]

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[37] USDA Press Office Release No. 0508.04, "Statement by John Clifford, Deputy Administrator Animal & Plant Health Inspection Service," November 23, 2004, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2004/11/0508.xml; (accessed July 6, 2005).
[38] USDA, APHIS, Factsheet, "Bovine Spongiform Encephalopathy (BSE) EPI Report."
[39] Id.
[40] USDA Press Office Release No. 0233.05, "Transcript of Media Conference With Remarks Made by Agriculture Secretary Mike Johanns, Dr. John Clifford, Chief Veterinary Officer, Animal Plant Health Inspection Service, and Dr. Danny Matthews, TSE Program Manager, Veterinary Laboratories Agency, Weybridge, England - Washington D.C.," June 24, 2005, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2005/06/0233.xml; (accessed July 6, 2005).
[41] Id.
[42] USDA APHIS. "Statement by USDA Chief Veterinarian John Clifford Regarding the Epidemiological Investigation into the Recently Confirmed BSE Case." 29 June 2005. http://www.aphis.usda.gov/lpa/issues/bse/bse_statement6-29-05.doc accessed 6 July 2005.
[43] USDA Summary of Epidemiological Findings of North American BSE Positive Cattle.

VII. Legal Grounds for the Petitioned Action

The Federal Meat Inspect Act authorizes the FSIS to promulgate rules and regulations necessary to give effect to the Act.[44] In this case, the interim rule has been published, the comment period has closed, and the agency has had ample time to review the comments received. There are no more legal impediments to issuance of a final rule.

Furthermore, the Administrative Procedure Act requires an agency to complete rulemaking and other matters presented to the agency "within a reasonable time."[45] In this case, in light of the most recent confirmed case of BSE and the substantial risk to both the public and the nation's economy, any further delay in issuance of a final rule could constitute unreasonably delayed agency action under the APA.

As courts in this Circuit have recognized, a number of factors must be considered to determine whether an agency's delay is unreasonable.[46] The first consideration is the length of time that has elapsed since the agency came under a duty to act.[47] Second, the "reasonableness of the delay must be judged in the context of the statute which authorizes the agency's action."[48] Third, "delays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake."[49] Fourth, "due consideration" should be given "in the balance to 'any plea of administrative error,

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April 2005. http://www.aphis.usda.gov/lpa/issues/bse/bse_epi_report_4-29-05.doc accessed 6 July 2005.

[44] 21 U.S.C. § 621 (2005).

[45] 5 U.S.C. § 555(b).

[46] In re International Chemical Workers Union, 958 F.2d 1144, 1149 (D.C. Cir. 1992); see also Grand Canyon Air Tour Coalition v. FAA, 154 F.3d 455, 476, n.21 (D.C. Cir. 1998).

[47] Cutler v. Hayes, 818 F.2d 879, 897 (D.C. Cir. 1987).

[48] Public Citizen Health Research Group v. Auchter, 702 F.2d 1150, 1158 n. 30 (D.C. Cir. 1983).

[49] Grand Canyon, 154 F.3d at 476, n.21, quoting TRAC, 750 F.2d at 80.

administrative convenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources."[50] Fifth, "the nature and extent of the interests prejudiced by delay" should also be taken into account. Finally, there need not be any "impropriety…in order to hold that agency action is unreasonably delayed."[51]

When these factors are applied here, it is clear that issuance of a final rule is not only good policy, but may also be legally required under the APA.

A. USDA's Delay in Finalizing Rule

Although "the time agencies take to make decisions must be governed by a 'rule of reason,'"[52] "there is no per se rule as to how long is too long."[53] In this case, the USDA's delay may be unreasonable, especially when considering that the agency has already fulfilled all of the legal requirements necessary to finalize the rule.

The interim final rule was published in the Federal Register on January 12, 2004, and comments were accepted between January 12, 2004 and July 1, 2004. During this period, 22,211 comments were received. A year has passed since the comment period closed, which is ample time for the agency to review the comments and issue a final rule. Moreover, in light of the fact that the comments were overwhelmingly in favor of finalizing the interim rule, coupled with the ongoing discovery of new cases of BSE, further delay cannot be lawfully justified.

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[50] In re ICWU, 958 F.2d at 1149, quoting Cutler, 818 F.2d at 898.
[51] In re United Mine Workers of Am. Intl. Union, 190 F.3d 545, 549 (D.C. Cir. 1999), quoting TRAC, 750 F.2d at 80.
[52] TRAC, 750 F.2d at 80 (other citations omitted)
[53] In re ICWU, 958 F.2d at 1149

B. USDA's Delay Is Unreasonable When Judged in the Context of the Human Health and Welfare Concerns Driving the FMIA

After discovering a BSE-infected cow in Washington State in December 2003, the USDA recognized the imminent threat to public heath presented by this discovery and implemented an emergency interim final rule which prohibits the slaughter of downed animals. However, despite this threat, the agency has yet to convert the interim rule to a final rule. Considering that the USDA published the interim rule approximately one month after the discovery of a BSE-infected cow in the United States, it is unreasonable that the agency has now waited one year to finalize that rule. This is especially true in light of the subsequent discovery of a BSE-infected cow in June 2005.[54]

The FMIA is crystal clear about the USDA's duty to protect the food supply. The FMIA states:

> "It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers."[55]

[54] USDA Press Office Release No. 0233.05, "Transcript of Media Conference With Remarks Made by Agriculture Secretary Mike Johanns, Dr. John Clifford, Chief Veterinary Officer, Animal Plant Health Inspection Service, and Dr. Danny Matthews, TSE Program Manager, Veterinary Laboratories Agency, Weybridge, England - Washington D.C.," June 24, 2005, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&contentid=2005/06/0233.xml; (accessed July 6,2005).

[55] 21 U.S.C. § 602 (2005).

The FMIA, as well as its implementing regulations, require the USDA to protect consumers by keeping the food supply safe and unadulterated. The FMIA authorizes the agency to implement regulations that allow it to realize the intent of the Act. Thus, issuance of a final rule protecting the food supply from BSE-infected cattle is a necessary step in fulfilling the USDA's public mandate under the FMIA.[56]

As numerous courts have explained, agency "[d]elays that might be reasonable in the sphere of economic regulation are less tolerable when human health and welfare are at stake."[57] In this case, as stated above, it is believed by scientific authorities, including the FSIS, the U.S. Food and Drug Administration, and the WHO, that vCJD, a fatal brain disease in humans, results from consumption of BSE-contaminated products.[58] Indeed, allowing non-ambulatory animals to be processed for human consumption threatens the safety of the food supply, as they are understood to be at heightened risk for BSE. Furthermore, because of the threat that BSE-contaminated cattle pose, as many as 50 countries have banned the import of beef from the United States, resulting in billions of dollars of lost revenue. Finalizing the interim final rule would not only satisfy the agency's obligations under the FMIA and help to protect the human health and welfare of consumers, but it would also help to give other countries confidence to relax their bans on U.S. beef imports, thus serving the interests of the nation's beef industry as well.

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[56] See Baur v. Veneman, 352 F.3d 625 (2nd Cir. 2003).
[57] Grand Canyon, 154 F.3d at 476, n.21, quoting TRAC, 750 F.2d at 80.
[58] USDA, FSIS, *Bovine Spongiform Encephalopathy—'Mad Cow Disease,'*; World Health Organization (WHO), *Variant Creutzfeldt-Jakob disease*, http://www.who.int/mediacentre/factsheets/fs180/en/, (accessed April 17, 2005).

C. USDA Cannot Maintain That It Cannot Issue a Final Rule Due to Error, Inconvenience, Practical Difficulty, or Competing Agency Priorities

In assessing whether a delay is unreasonable under the APA, due consideration should also be given to "any plea of administrative error, administrative convenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources."[59] In this case, the USDA cannot legitimately claim that issuing a final rule is somehow impossible due to any of these factors. As discussed above, the agency's work is already done. The rule has been published, the comment period has closed, and the comments overwhelmingly support the interim rule. All the agency has left to do is publish the final rule in the Federal Register. There can be no claim that this final administrative step is inconvenient, poses a practical difficulty, or cannot be accomplished because of competing agency priorities.

D. Petitioners Are Prejudiced by USDA's Delay and Have No Other Remedy

In considering the USDA's delay, the "nature and extent of the interest prejudiced by delay" must also be taken into account.[60] Here, not only are petitioners prejudiced by the agency's delay in finalizing the interim rule, but the public and the beef industry are also prejudiced and potentially harmed. Issuance of a final, permanent ban on downer cattle entering slaughter is the only way the public and countries with whom the United States trades can feel confident that the nation's food supply is safe.

Banning downed cattle from the human food supply also promotes the public's interest in the humane treatment of farm animals. Downed animals sent to slaughter

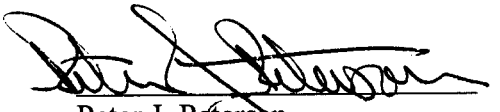
[59] In re ICWU, 958 F.2d at 1149, quoting Cutler, 818 F.2d at 898.
[60] UMWA, 190 F.3d at 549, quoting TRAC, 750 F.2d at 79-80.

suffer immeasurably. They're often forced to walk with broken bones and other painful injuries, or when they can't move, the animals are forcibly dragged by chains or pushed by a bulldozer. A permanent ban on processing downed cattle would provide an incentive for producers and transporters to improve the handling and care of animals to make sure they don't go down in the first place. Thus, the public's heath, the beef export industry, and the welfare of cattle raised for human consumption are all dependent on the agency finalizing the interim rule.

VIII. Conclusion

As is abundantly clear from the foregoing discussion, finalizing the interim rule banning all downed cattle from entering the food supply is essential to ensure our food supply is safe, that our markets remain open, and that animals are treated in a humane and compassionate manner. After the interim final rule was published, more than 21,000 Americans submitted comments, and the comments were overwhelmingly in favor of the downer policy. It is time for the USDA to listen to its constituents and immediately finalize the interim rule, as required by the FMIA and the APA.

Respectfully Submitted,



Peter J. Petersan
Deputy Director, Animal Protection Litigation
Peter A. Brandt
Litigation Fellow
THE HUMANE SOCIETY OF THE UNITED STATES
2100 L St., N.W.
Washington, DC 20037
202-452-1100

CERTIFICATE OF SERVICE

I, Jessica Spite, hereby certify that a copy of the foregoing "Petition for Rulemaking," and all materials in support thereof, was served this 7th day of July, 2005, by First Class U.S. Mail, to:

Secretary Mike Johanns
United States Department of Agriculture
14th St. and Independence Ave., S.W.
Room 200-A
Washington, DC 20250

Administrator Dr. Barbara Masters
Acting Administrator,
USDA, Food Safety and Inspection Service
14th St. and Independence Ave., S.W.
Washington, DC 20250

Jessica Spite