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MAD COW DISEASE: IS THERE AN APP FOR THAT?

Sara Gonzalez-Rothi Kronenthal

INTRODUCTION

On December 4, 2013, the United States Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) published a final rule relaxing animal product importation restrictions originally intended to protect the American meat supply from mad cow disease. Consumers may rationally believe that APHIS took this action because it was safe to do so: that the threat of bovine spongiform encephalopathy (BSE), the scientific name for mad cow disease, had passed. Certainly the federal government entity charged with ensuring the health of animals in the human food chain would not relax beef importation regulations without due diligence; this, however, may not necessarily be the case.

While food safety rules target the regulated commodity, the stringency of regulation also provides incidental information to users. For example, consumers are likely to assume that products with relaxed regulations are safe to use. History indicates that in the case of BSE, the precautionary principle is the exception more than the rule. The governmental response to the BSE epidemic is to assume that beef is safe until proven otherwise. Further complicating matters, the patchwork of regulatory jurisdiction over meat and meat products in the United States has yielded seemingly contradictory information about the risk posed by BSE. Given numerous unresolved questions about the prevalence, mechanisms, prevention, and containment of mad cow disease, the government has made it incredibly

* The views expressed herein are solely those of the author and do not necessarily reflect the official policy or position of the Author’s current, past, or future employers. Sincere thanks to Professor William S. Eubanks II, Dr. Kenneth Heilman, M.D., and Dr. Bayard Miller, M.D. for their thoughtful contributions. Thanks also to Connor Egan, Editor in Chief, and the talented staff of the Kentucky Journal of Equine, Agriculture, and Natural Resources Law. Finally, this author owes enduring appreciation for the patience and support of Craig Kronenthal and Drs. Leslie, Ricardo, and Elisa Gonzalez-Rothi.

difficult for average consumers to make informed decisions about their food.

Part I of this Article provides background information on the beef industry and the history of BSE. Part II describes the regulatory patchwork surrounding BSE. Finally, Part III analyzes how the regulatory patchwork leaves American consumers susceptible to the BSE's risks and recommends a centralized database to provide consumer information about that risk.

I: Background

A. The American Beef Industry

In the United States, beef is big business. In 2012 alone, the retail value of the beef industry was $85 billion. Americans consumed close to twenty-six billion pounds of beef in 2013. That same year, the United States exported two-and-a-half billion pounds of beef, primarily to Canada, Japan, Mexico, South Korea, and Hong Kong. There are over 729,000 different U.S. beef cow operations, with ninety percent of that figure being herds of less than one hundred animals.

B. Regulatory Framework

Regulation of food in the United States is complex. As modern technology advances and diseases emerge or evolve, food laws often lag behind. Regulation of animal products commonly found in international trade presents even greater challenges. Recognizing, identifying, and containing animal-related food-borne pathogens are akin to a very rapid and global game of whack-a-mole.

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3 Id.
5 Id.
A regulatory patchwork of federal agencies implement various authorities related to detection, prevention, and containment of BSE: APHIS regulates animal health and disease, the Food Safety and Inspection Service (FSIS) regulates the safety of meat in the human food supply, the Food and Drug Administration (FDA) regulates the use of ruminant products in animal feed, non-meat human food, and cosmetics, the Centers for Disease Control (CDC) maintains surveillance for human disease, the National Institutes of Health (NIH) conducts research on BSE, and the Environmental Protection Agency (EPA) registers and regulates the sale of prion-related products.

C. History of Mad Cow Disease

Aside from the regulatory challenges in addressing BSE on a national scale, the disease is biologically complex. Initially identifying the problem was particularly difficult because BSE is not transmitted by a typical pathogen like a virus or a bacterium. BSE is related to an infectious modification of a protein that would otherwise be normal tissue. In 1954, Bjorn Sigurdsson was working with sick sheep in Iceland and named the mechanism of their scrapie disease a “slow virus.” For decades, similar diseases in humans were also considered slow viruses. In 1982, Stanley

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12 Id. at 13363.
13 See generally Kuru, MEDLINE PLUS, http://www.nlm.nih.gov/medlineplus/ency/article/001379.htm (last updated Nov. 10, 2012) (For example, populations in New Guinea that historically participated in ritual consumption of human brain tissue developed nervous system disease called Kuru); see also CJD (Creutzfeldt-Jakob Disease, Classic), CTR. FOR DISEASE CONTROL & PREVENTION, available at http://www.cdc.gov/ncidod/dvrd/cjd/ (last
Prusiner finally termed the mechanism of disease as a "prion," because it was both proteinaceous and infectious. An infectious prion protein unfolds and refolds abnormally.

Genetic mutation of infectious prions can be inherited. Prions can also be transmitted from one species of animal to another. When a prion disease is transmitted between species, there is a prolonged incubation period in the new animal. This is known as the "species barrier."

Scrapie, BSE, Creutzfeldt-Jakob (CJD), and chronic wasting disease (CWD) are resistant to ultraviolet and ionizing radiation. These transmissible spongiform encephalopathies (TSEs) progress until the death of the host and never produce a sign of an immune response. As a result, testing is only possible post-mortem. BSE and its human expression variant Creutzfeldt-Jakob Disease (vCJD) result in rapidly progressive dementia and are invariably fatal prion diseases. A recent study suggests that widespread low-dose exposure to BSE may correlate to vCJD "carrier status" in as many as one in every 2000 residents in the United Kingdom.

On average, BSE incubates for five years before the infected cow will show symptoms. However, most beef cattle are slaughtered before their third birthday. As a result, the majority of exposed beef cattle never exhibit the disease. Studies indicate that healthy cows ingesting as little as

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updated Dec. 9, 2014) (For example, classic Creutzfeldt-Jakob disease is a sporadic spongiform encephalopathy in humans generally affecting individuals in their late sixties.; see also Paul Brown et al., Iatrogenic Creutzfeldt-Jakob Disease, Final Assessment, 18(6) EMERGING INFECTIOUS DISEASES 901 (June 2012), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3358170/ (The fundamental misunderstanding in the mechanism of prion disease resulted in hundreds of iatrogenic cases where humans (medical professionals or surgical patients) came into contact with CJD-contaminated tissues via medical research of cadaver samples, corneal and dura mater transplantation, human growth hormone treatment, blood products, or use of contaminated penetrating instruments.).

14 Prusiner, supra note 11, at 13365.
15 Id. at 13378.
16 Id. at 13373.
17 Id. at 13374 (Prusiner inoculated mice with scrapie, the prion disease that affects sheep.).
18 Id. at 13372.
19 Id.
20 Id. at 13364.
21 Id.
23 Prusiner, supra note 11, at 13375.
24 Id.
25 Id.
one gram of infected tissue can develop BSE. Because the abnormal prion is not deactivated by traditional sterilization measures, slaughterhouse, butchering, and food preparation equipment may transmit the disease from one asymptomatic contaminated animal to an exponential number of otherwise safe meat products.

D. Signs of an Epidemic

The first cases of BSE were confirmed in the United Kingdom in 1986. Examiners studied the brains of two sick cows and found signs similar to scrapie in sheep. It is likely there were prior undiagnosed instances of BSE, potentially even decades earlier. In 1988, the U.K. banned feeding ruminant-derived meat-and-bone-meal (MBM) to ruminants. By 1993, a staggering 1000 new cases were being reported each week. When the first case of vCJD was confirmed in 1996, the U.K. instituted a ban on feeding any mammal protein to farm animals. The European Union followed suit in 2001.

E. BSE in North America

In 1997, the United States and Canada both banned the use of “specific risk materials” (SRM) in cattle feed, including brain, spinal cord, retina, and vertebral column matter from cattle thirty months and older,
and small intestine and tonsils from cattle of all ages. Even within the restrictions of the feed ban, the law does allow for equine protein (including SRM), porcine protein (including SRM), poultry protein, fish protein, and ruminant blood, blood products, milk, milk products, gelatin, and tallow (fat) with less than 0.15% insoluble impurities to be fed to cattle intended for human consumption. In May 2003, the first case of BSE in a Canadian-born cow was confirmed in Canada. In response, the United States banned importation of Canadian beef.

On December 23, 2003 an adult dairy cow born in Alberta, Canada and slaughtered in Washington State tested positive for BSE. Although the animal was imported from Canada, the finding prompted the USDA to prohibit meat products from non-ambulatory American cattle ("downers") from entering the human food supply. June 2004 marked the first U.S. death related to vCJD. Nearly ten years later, the CDC confirmed the fourth U.S. death attributable to vCJD.

Since the implementation of several rules intended to safeguard the American meat supply, there have been three additional confirmed domestic cases of BSE. A twelve-year old cow born and raised in Texas tested positive for BSE in 2005. A cow over ten years old was diagnosed

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35 Id.; see also WASH. STATE DEPT. OF AGRIC., Animal Proteins Prohibited in Ruminant Feed & Cattle Materials Prohibited in all Animal Feed (Aug. 2013), http://agr.wa.gov/foodanimal/animalfeed/Publications/ProhibMatDefs.pdf (discussing which animal products can be used in animal feed).
41 Jon Herskovitz, Texas Man Fourth in U.S. to Die from Rare Brain Disease: CDC, REUTERS (June 5, 2014, 1:45 PM), http://www.reuters.com/article/2014/06/05/us-usa-texas-illness-idUSKBN0EG2FW20140605.
42 Substances Prohibited From Use in Animal Food or Feed, 73 Fed. Reg. 22,720 (April 25, 2008).
in 2006 in Alabama.\footnote{id} Both animals were born prior to the 1997 ruminant feed ban, and there is at least the potential they were infected before the ban went into effect. Yet, as recently as 2012, a California dairy cow born in 2001 tested positive for BSE.\footnote{44}

Interestingly, there is a higher incidence of BSE in dairy cattle than in beef cattle.\footnote{45} Experts believe this may be related to the fact that beef calves generally nurse, are weaned, and then primarily eat grass with limited exposure to processed feeds.\footnote{46} Dairy calves typically are not allowed to nurse,\footnote{47} but are instead given milk substitutes and concentrated protein feeds that may contain contaminated material.\footnote{48} This lower incidence of BSE in beef cattle does not lessen the risk of zoonotic transmission to humans. Dairy beef enters the human food supply to limit herd size, in cases where reproductive failure or low milk production exist,\footnote{49} or via the harvest of Holstein bull calves.\footnote{50}

II: REGULATORY PATCHWORK

A. Testing

Given the negative market implications of uncertainty regarding BSE contamination, several producers attempted to assure consumers their products are safe. APHIS regulates testing for BSE. There are three testing options: the Bio-Rad Laboratories immunoassay "rapid" test, the Western blot test, and the immunohistochemistry (IHC) test.\footnote{51}

\footnote{43} Id.
\footnote{45} Smith & Bradley, supra note 28, at 186.
\footnote{46} Id.
\footnote{47} Id.
\footnote{48} It is industry practice is sell dairy calves at two to five days old. See generally John W. Comerford et al., Dairy Beef Production, PENN ST. COL. OF AGRIC. EXTENSION (2008), http://extension.psu.edu/business/ag-alternatives/livestock/beef-and-dairy-cattle/dairy-beef-production.
\footnote{50} Because the males do not produce, steers are often harvested at about one year. See generally Comerford, supra note 47.
In the earliest detectable phase, even before a cow exhibits symptoms of the disease, BSE is found in the “obex,” a two to three millimeter portion of the brainstem.\textsuperscript{52} The rapid immunoassay requires a sample of the obex.\textsuperscript{53} The condition of the sample is critical to an accurate reading.\textsuperscript{54} In compliance with federal regulation, cattle in the United States are slaughtered using a captive bolt gun to the frontal lobe of the brain,\textsuperscript{55} either with instruments that penetrate the skull or non-penetrating concussion stunners.\textsuperscript{56} The force of the impact or subsequent processing to remove the central nervous system tissues can damage the brainstem or the obex, thereby jeopardizing the integrity of the sample.\textsuperscript{57} Indeed, the regulations defining humane use of a penetrating captive bolt gun describe the mechanism of action as “physical brain destruction.”\textsuperscript{58}

In Japan and the European Union, all slaughtered animals are given the rapid test.\textsuperscript{59} If the results are inconclusive, both the IHC and the Western blot are administered to conclusively rule out infection.\textsuperscript{60} In the United States, the rapid test is only given to a select portion of slaughtered animals.\textsuperscript{61} The USDA conducts “surveillance” to “identify any rise in BSE prevalence in this country.”\textsuperscript{62} From June 2004 through September 2006, following the discovery of BSE in the United States, the USDA ran an enhanced surveillance program testing close to 800,000 cattle.\textsuperscript{63} Several of the rapid tests yielded inconclusive results.\textsuperscript{64} Of those, one was confirmed

\textsuperscript{52} Alexandre Dobly et al., Sampling Quality in Bovine Spongiform Encephalopathy Routine Monitoring in Belgium—Short Communication, 83(3) VETERINARSKI ARHIV 341, 342 (2013).
\textsuperscript{53} Id.
\textsuperscript{54} Id.
\textsuperscript{55} 9 C.F.R. § 313.15 (2007).
\textsuperscript{56} 9 C.F.R. § 313.15 (b)(1)(i).
\textsuperscript{57} See Dobly et al., supra note 52.
\textsuperscript{58} 9 C.F.R. § 313.15(b)(1)(i).
\textsuperscript{60} Id.
\textsuperscript{62} See id.
BSE positive. In response to pressure from beef producers, and when rapid tests yielding inconclusive results on two animals in June 2004 were later confirmed negative for BSE, the USDA stopped announcing preliminary rapid test findings.

Since that time, the USDA has reduced surveillance and now only tests 40,000 slaughtered cattle per year. In 2013, close to thirty-three million heads of cattle were slaughtered in the United States. Given these projections, the USDA only tests around one-tenth of one percent of slaughtered cattle. Through this very limited surveillance protocol, the USDA estimates the prevalence of BSE at "the very low level of less than 1 case per one million adult cattle." The USDA argues that compulsory testing of each slaughtered animal could in fact negatively impact food safety:

"Testing all slaughter cattle for BSE could produce an exceedingly high rate of false negative test results and offer misleading assurances of the presence or absence of disease. Simply put, the most effective way to detect BSE is not to test all animals, which could lead to false security, but to test those animals most likely to have the disease, which is the basis of USDA's current program."

The USDA does not administer its 40,000 annual rapid tests, and its 800,000 enhanced surveillance tests given at the height of the epidemic, to a random sample of slaughtered cattle. The USDA primarily surveys only animals presenting clinical symptoms of disease, including "downers" or otherwise sick animals generally unfit for human consumption. If a rapid
test of a target animal is inconclusive or positive, the USDA uses a second testing method.73

The USDA's "primary confirmatory test" is the IHC.74 Like the rapid test, the IHC requires intact samples of the obex.75 The tissue is stained and observed under a microscope to determine whether visual indications of infection are present.76 In contrast to the rapid and IHC tests, the USDA can use the Western blot test when the obex tissue is degraded to the point at which it is impossible to visually identify changes.77 According to the USDA Western blot protocol, if a sample is "not suitable for IHC," the tissue is exposed to an enzyme that destroys normal proteins and leaves only abnormal prion proteins, which are then further analyzed for prion disease.78

B. Voluntary Testing

In the United States, the larger groups in the beef industry opposed voluntary testing because of concerns that it would lead to mandatory testing.79 Some producers, however, recognized a market opportunity in testing each slaughtered animal. For example, in 2004, Creekstone Farms sought to purchase rapid-BSE test kits for its Black Angus beef cattle to recapture overseas revenue that had declined precipitously out of concern over the safety of American beef.80 Gateway Beef Cooperative, comprised of fifty-eight smaller operations, also requested USDA approval to test its cattle.81 The Ranchers-Cattleman Action Legal Fund joined the call for voluntary testing as well.82

73 Id.
75 Id.
76 Id.
77 Id.
78 Id.
79 Berlowitz, supra note 59, at 630.
80 Creekstone Farms Premium Beef v. Dep't of Agric., 539 F.3d 492, 496 (D.C. Cir. 2008).
82 See id. at 2.
The USDA thwarted this savvy business decision with its interpretation of a law enacted long before the discovery of infectious prions. The Virus, Serum, and Toxin Act of 1913 (VSTA) requires USDA approval of 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.”\(^{83}\) VSTA defines “analogous products” as “[s]ubstances . . . intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity.”\(^{84}\) The Act defines “treatment” as “prevention, diagnosis, management or cure of diseases of animals.”\(^{85}\) As such, the manufacturer of the BSE rapid immunoassay needed USDA approval to sell the kits to producers.

USDA denied the sale, however, claiming 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.”\(^{86}\)

After the USDA’s denial, Creekstone brought suit, contending that the restricted use of biological products and the definition of “treatment” were ultra vires.\(^{87}\) On cross motions for summary judgment, the district court ruled that the USDA was able to restrict the use of biological products under VSTA, but that the USDA interpreting the post-mortem BSE test kits as “treatments” was outside the scope of the Act.\(^{88}\) Giving substantial deference to the agency, the D.C. Circuit held that both the USDA’s restricted use and interpretation of the test as “treatment” was appropriate under VSTA.\(^{89}\) As a result, there is a de facto prohibition on voluntary testing for BSE, as well as a concomitant bar to American beef consumers seeking to absolutely limit BSE exposure.

\(^{85}\) 9 C.F.R. § 101.2(3).
\(^{87}\) Creekstone Farms Premium Beef v. Dep’t of Agric., 539 F.3d at 497.
\(^{88}\) Id.
\(^{89}\) Id. at 492.
Inability to walk is often a symptom of BSE. In a 2004 interim rule, FSIS banned the slaughter of non-ambulatory “downer” cattle, defined as those that “cannot rise from a recumbent position,” from use in the human food supply. Because downer cows are considered to be at high risk for infection, the rule requires prompt euthanasia and condemnation rather than slaughter. FSIS finalized the regulation in 2007. The rule, however, provided that cattle that are unable to walk due to an injury sustained after an ante-mortem inspection, as certified by a Public Health Veterinarian (PHV) on a case-by-case basis, could be eligible for slaughter rather than condemnation.

An undercover investigation in 2008 discovered the use of inhumane tactics to force a non-ambulatory animal to stand in order to pass the ante-mortem inspection, qualify for PHV certification, and avoid condemnation at a slaughter facility. This is particularly troubling because the incubation period for BSE is five years, meaning that even once the disease is active, it can take months for an infected animal to show symptoms. A downer cow prodded to stand and pass inspection can still pose a serious food safety risk. Because of that possibility, FSIS amended the downer cattle regulations and struck the exemption for post-inspection injury in 2009.
The rule still allowed veal calves that were too cold or tired to walk to be treated rather than condemned. On March 13, 2013, however, FSIS granted a petition to repeal the provision allowing the set-aside of downer veal calves. Whether new regulations will require condemnation of downer calves remains to be seen, but in its response to the petition for rulemaking, FSIS predominantly references animal welfare issues rather than food safety considerations.

D. EPA Regulation of Prion-related Substances

After the outbreak of BSE, legal scholars suggested that the EPA had jurisdiction over substances purported to destroy, deactivate, or prevent the spread of infectious prions. In practice, since September 2003, the EPA interprets the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to confer regulatory authority over prion-related products. Though prions are not actually alive, the EPA maintains that infectious prions have several of the characteristics of a “pest” pursuant to FIFRA. In 2013, the EPA completed rulemaking consistent with the agency’s long-standing legal interpretation:

EPA declares a prion (i.e., proteinaceous infectious particle) to be a “pest” under FIFRA, and amends its regulations to expressly include prion within the regulatory definition of pest. Since 2003, EPA has considered a prion to be a pest under FIFRA, so a product intended to reduce the infectivity of any prion on

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inanimate surfaces (i.e., a “prion-related product”) is considered to be a pesticide and regulated as such.

The final rule requires “efficacy data to support the registration of all end-use products which bear label claims to reduce infectivity of prions.” In so doing, the regulation prevents producers from misleading consumers into using a product because of the belief the product will reduce their exposure to infectious prion proteins.

E. Country of Origin Labeling

The 2002 Farm Bill included a requirement that perishable foods be labeled with the name of the country where they originated; however, the beef industry remained divided as to labeling requirements. Groups representing domestic beef producers generally supported mandatory labeling, while those primarily representing packers and processors preferred a voluntary scheme. Congress delayed Country of Origin Labeling (COOL) requirements for some foods, including beef, until September 30, 2008. The 2008 amendments to COOL specify that the “country of origin” for beef, lamb, pork, chicken, goat, or venison is based on where the animal was born, raised, and slaughtered. In 2009, the USDA Agricultural Marketing Service (AMS) finalized COOL regulations for beef. The 2009 COOL required products containing commingled meat to be labeled with a list of all countries of origin. The rule did not require specifying what production steps occurred in each country.
2012, the World Trade Organization found that the 2009 rule created barriers to trade inconsistent with U.S. trade agreements.\(^{113}\) In response, AMS strengthened COOL in 2013.\(^{114}\) The new rule requires the label for muscle cuts of meat to include detail as to whether production steps for a particular product have occurred in different countries.\(^{115}\) For example, beef from a cow born and raised in the United States but slaughtered in Mexico would be labeled as such, rather than simply labeled a product of the United States and Mexico." The revised 2013 COOL regulation also eliminates flexibility for commingled meat products with different countries of origin.\(^{116}\)

The requirement to accurately label commingled meat products has further highlighted the divide between beef products for which value will increase with stringent labeling requirements and products for which the added expense will outweigh potential market benefit. The American Meat Institute immediately challenged the 2013 rule as exceeding the statutory authority granted to AMS and as an unconstitutional compulsion to speak in violation of the First Amendment.\(^{117}\) The U.S. Cattlemen's Association and Food and Water Watch intervened to support AMS.\(^{118}\) Because of international trade implications, the 2009 COOL requirements proved controversial.\(^{119}\) The 2013 rule is facing similar scrutiny.\(^{120}\)

The most recent challenge to the rule centers on whether the COOL regulation violates First Amendment speech protections.\(^{121}\) While labeling requirements trigger First Amendment considerations, compulsory disclosure is less likely to infringe upon constitutional protections than a

\(^{113}\) Id.


\(^{115}\) Id.

\(^{116}\) Id.


\(^{118}\) Id.


\(^{120}\) Am. Meat Inst. v. U.S. Dep't of Agric., 760 F.3d 18 (D.C. Cir. 2014).

\(^{121}\) Id.
ban on speech,\textsuperscript{122} especially because the consumer interest in factual information is substantial.\textsuperscript{123} With regard to the 2013 COOL regulation, the D.C. Circuit in \textit{American Meat} specifically considered the public health implications of labeling:

[H]ere we think several aspects of the government's interest in country-of-origin labeling for food combine to make the interest substantial: the context and long history of country-of-origin disclosures to enable consumers to choose America-made products; the demonstrated consumer interest in extending country-of-origin labeling to food products; and the individual health concerns and market impacts that can arise in the event of a food-borne illness outbreak.\textsuperscript{124}

Though not specifically providing information about BSE infectivity, COOL requirements do provide American consumers with important information about the source of food products.\textsuperscript{125} This "[c]ountry-of-origin information has an historical pedigree that lifts it well above 'idle curiosity.'"\textsuperscript{126} The 2013 revisions require labeling of each production step of meat products, both commingled and whole, which fundamentally improves the precision of information pertaining to the meat.\textsuperscript{127} Consumers can then rely upon the labels in making decisions about whether to avoid meat products born, raised, or slaughtered in certain countries.\textsuperscript{128} While the

\textsuperscript{123} \textit{Am. Meat Inst.}, 760 F.3d, at 23.
\textsuperscript{124} Id.
\textsuperscript{126} Id.
\textsuperscript{127} Id. at 21. See also, Mandatory Country of Origin Labeling, 78 Fed. Reg. 31,367 (May 24, 2013).
\textsuperscript{128} See, e.g., Wendy A. Johnecheck, \textit{An Examination of Whether U.S. Country of Origin Labeling Legislation Plays a Role in Protecting Consumers from Contaminated Food}, 21 STAN. L. & POL'Y REV. 191, 207 (2010) ("First, in the case of a food-borne illness outbreak or food recall in which regulatory or industry officials have successfully narrowed down the source of the contamination to products from a single country or region, consumers could use an origin label to avoid a given product from a particular country . . . . The second, and more proactive, way in which consumers could use country-of-origin information to reduce the risk of consuming contaminated food is through basing their purchase decisions on a country's safety record for a given food item.").
rule has survived every domestic legal challenge to date,\textsuperscript{129} it remains to be seen whether successful implementation will yield the public health benefits sought.

Furthermore, international pressure may influence the fate of country-of-origin labeling requirements.\textsuperscript{130} In October 2014, a World Trade Organization (WTO) compliance panel found that the 2013 COOL might pose an impermissible technical barrier to trade, even though it serves a "legitimate objective"\textsuperscript{131} and less restrictive alternatives are not readily apparent.\textsuperscript{132}

In an interesting turn of events, Australia's government, which opposed the U.S. COOL in 2014, seems poised to implement similar food disclosure requirements this year. In response to an outbreak of foodborne hepatitis A, in February 2015, the Prime Minister directed his cabinet to develop country-of-origin labeling requirements for food products entering Australia.\textsuperscript{133} Whether and how the WTO Dispute Settlement Body will address the October 2014 report or potential future origin disclosure requirements remains to be seen.

\textit{F. Important Regulations: The Comprehensive Rule}

Following the confirmed presence of BSE, the U.S. implemented importation limitations, and even outright bans, from certain countries. Live cattle and ruminant products from countries where BSE was


\textsuperscript{131} Id. at 138.

\textsuperscript{132} Id. at 181.

confirmed were banned in 1989. In 1991, the USDA further prohibited the importation of beef from several specific countries. In addition, the ban included several countries listed as having inadequate surveillance or restrictions on importation.

Beef exported from the United States was likewise subjected to a foreign importation ban. Before, and even since, the discovery of BSE infected cattle in the United States, Japan has been one of the largest export markets for American beef. From 2003 until 2006, Japan halted importation of U.S. cattle and cattle products entirely. Upon lifting the full ban, Japan accepted imports of U.S. beef only from cattle fewer than twenty months old. The international standard for BSE prevention is generally thirty months. The American beef industry pressured U.S. officials to engage in trade talks urging Japan to accept the 30-month standard. The beef industry also urged APHIS to finalize adoption of BSE-related importation standards of the World Organisation for Animal Health (OIE). In 2012, the USDA began the process when it proposed the implementation of the OIE system for classifying regions based on BSE risk.

The final rule relaxing these importation restrictions became effective on March 4, 2014. According to APHIS:

This final rule will bring USDA's BSE import regulations in line with international standards, which call for countries to base their trade policies on the actual risk of cattle and cattle products

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136 9 C.F.R. § 94.19(a)(2).
138 Id.
harboring the disease. As a result, commodities that are now restricted but pose negligible risk for BSE could be imported. Commodities that present a risk of BSE would continue to be restricted.\textsuperscript{141}

This "comprehensive rule" establishes a classification system for country of origin and infectivity based on the OIE-determined relative risk of BSE as negligible, controlled, or undetermined.\textsuperscript{142} Classification is based on self-reported data, which the OIE Scientific Commission and the OIE BSE ad hoc group approve.\textsuperscript{143} The rule allows for importation of deboned skeletal cattle meat from all countries, regardless of BSE risk rating.\textsuperscript{144} APHIS justifies this provision on the basis that the most highly infectious tissues are removed and the country of origin must comply with "steps to prevent the contamination of the products with SRMs."\textsuperscript{145}

In response to the draft rule, commenters have suggested that although the OIE standards mirrored in the comprehensive rule are internationally recognized, they allow for more risk of BSE infection than other international standards.\textsuperscript{146} APHIS responded, “[a]s part of the United States’ consideration of OIE drafts, APHIS distributes these drafts to the U.S. livestock and aquaculture industries, veterinary experts in various U.S. academic institutions, and other interested persons for review and comment.”\textsuperscript{147} It is interesting to note that each explicitly listed reviewing entity relates to animal business or animal health.\textsuperscript{148} APHIS does not indicate whether there was consultation with public health professionals.\textsuperscript{149} It remains to be seen whether or not the comprehensive rule delimiting importation of certain cattle products from previously banned regions will result in greater exposure to BSE-infected materials.

\textsuperscript{142} See id.
\textsuperscript{143} Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products, 78 Fed. Reg. 72,979, 72,983 (Dec. 4, 2013) (to be codified at 9 C.F.R. pts. 92, 93, 94, 95, 96, and 98).
\textsuperscript{144} Id.
\textsuperscript{145} Id.
\textsuperscript{146} Id.
\textsuperscript{147} Id. at 72,982.
\textsuperscript{148} Id.
\textsuperscript{149} Id.
III: ANALYSIS

The government's response to BSE creates considerable confusion for the American consumer. Moreover, simple consumer access to information is not sufficient to adequately ensure food safety because knowledge alone does not necessarily yield meaningful choice. Though the probability is low, the gravity of contracting vCJD is severe, and it requires the utmost caution to limit exposure to BSE.

Currently, the burden of eliminating exposure falls squarely upon the individual consumer. Loopholes in the U.S. testing regime and recent modifications to importation restrictions leave the consumer who wants certainty with only one choice: abstention from all bovine products. For those consumers willing to accept, but seeking to manage risk, the current domestic food system fails to provide sufficient tools.

In addition to actually limiting risk itself, the relative stringency—or laxity—of regulation provides consumers with important signals about risk. This is especially true with widely consumed products. Consider public perception of caffeine and nicotine. Both chemicals are low-level secondary stimulants with addictive properties. Nicotine-containing products are highly regulated with labeling and minimum age purchasing requirements. There is no regulation, however, requiring information about the precise amount of caffeine, a warning as to the stimulant properties, or a minimum age for purchasing caffeinated food products. Average consumers are more aware of the risks associated to nicotine than of those related to caffeine.

150 See Johneccheck, supra note 128, at 208. ("Furthermore, even where food safety inspection information is readily accessible to consumers, the broader context surrounding the data needs to be understood in order to accurately assess the relative risk of consuming contaminated food. For example, the reporting of fourteen cases of Bovine Spongiform Encephalopathy (BSE) in Canadian cattle relative to three U.S. reported cases has been misconstrued as evidence that consuming Canadian beef products presents a higher food safety risk than consuming U.S. beef products. However, a more precise assessment reveals that the U.S. and Canadian production systems are similar in structure and are largely integrated, and it is quite probable that the discrepancy in BSE cases reported between the two countries is a function of the relatively enhanced Canadian surveillance system, which randomly tests more at-risk cattle than the United States despite slaughtering fewer animals.").

In contrast to nicotine or caffeine, which have direct characteristic influence on the physiology of the consumer, an overwhelming majority of beef cattle have an infinitesimally small risk of contracting and transmitting BSE to humans. Excessive precaution could result in significant unintended, detrimental, and unnecessary consequences to the economy, food scarcity, and nutritional deficiency in populations reliant on beef as a primary protein or iron source. Yet BSE is highly infective and the consequences of contracting the disease are grave.

While some recent federal regulatory actions increase the information regarding the source of meat, others actually limit consumer choice. By stretching the VSTA to the outer limits of its authority to prohibit voluntary testing by producers, the USDA is limiting the option of American consumers to be certain that they are eating BSE-free beef. On the other hand, the EPA codified its interpretation of FIFRA to assure consumers that prion-related product claims are based on qualitative data. While AMS is ensuring consumers know the origin of meat products, APHIS is easing importation restrictions.

The missions of the respective agencies, the overlap, and the gaps in the regulatory patchwork provide context for their seemingly differential understanding of BSE risk. For example, the AMS aims to facilitate the marketing of U.S. products. Requiring stringent country of origin labeling aids that goal. APHIS is required to ensure animal and plant health, but not human health. This explains the primary emphasis on enforcement of the feed ban rather than importation restrictions. FSIS is tasked with ensuring the safety of beef for human health. In the context of importation, this is accomplished through FSIS approval of the procedures used in foreign countries as equivalent to U.S. standards.

In an increasingly globalized food system, enforcement of any regulation is a challenge. Even enforcement of BSE regulations on domestic

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153 See generally Chang, supra note 107.

entities has proven less than successful. Implementation of the feed ban alone prompted two scathing Government Accountability Office reports indicating significant compliance failures. It remains to be seen whether even the precise and minimally burdensome COOL requirements will ultimately be upheld, and enforcement will pose its own unique challenge.

No single agency is responsible for the intersection of animal and human health in the context of the American food system. There is also no integrated statute authorizing prevention, containment, and enforcement authority for both BSE and vCJD. As a result, existing federal agencies are left fitting square pegs into round holes. By contorting authorities written without infectious prion proteins in mind, pieces of the regulatory puzzle are left missing.

In the absence of a comprehensive and coordinated federal blueprint to limit BSE exposure, administrative actions at the federal level can and should be taken promptly to maximize choice and consumer protection. Specifically, APHIS, AMS, FSIS, and CDC should establish a centralized public Internet database of global BSE and vCJD information.

There is a model of a government-maintained database of publicly accessible consumer information. The website Recalls.gov is a joint initiative of the Consumer Products Safety Commission, the National Highway Traffic Safety Administration, the Coast Guard, the Food and Drug Administration, the USDA, and the EPA. With one click, anyone can find current information about federal recalls of consumer products, motor vehicles, boats, food, medicine, cosmetics, and environmental products. The website proclaims, "To provide better service in alerting the American people to unsafe, hazardous or defective products, six federal agencies with vastly different jurisdictions have joined together to create ... a 'one stop shop' for U.S. Government recalls." This site even allows consumers to report dangerous products.

The implementation of the comprehensive rule and COOL provide a timely opportunity to establish such a repository. A BSE-vCJD database should follow the Recalls.gov model. For each country, the site should include information as to the OIE relative risk rating, the BSE testing regime, common harvest methods, confirmed positive BSE incidences, and relevant feed regulations of each country. As prion disease research yields more information about risk and infectivity, the website could be updated in real-time.

Such a database will maximize the value of COOL to individual consumers because the information provided will give meaning and context to the country-of-origin designation. Furthermore, because American per capita beef consumption is high, a transparent database will induce a race-to-the-top. Higher-risk beef producing countries will have added incentive to adopt precautionary practices. Finally, a BSE-vCJD database would be inexpensive to develop and maintain and would not burden producers.

CONCLUSION

BSE and vCJD are an epidemiologic Pandora's Box. With unreliable enforcement and confusing regulatory protections, consumers are left in the dark. Though the worst of the BSE epidemic is no longer front-page news, the stakes are too high to take chances in the face of continued scientific uncertainty. For the benefit of American consumers, and ultimately the beef industry, the government must recognize and appropriately address the risk. With widespread access to the internet and new labeling requirements, failure to develop a centralized online BSE-vCJD risk database would be absurd.