

RECEIVED
FSIS DOCKET ROOM
04 MAY -6 AM 10:00

April 29, 2004

FSIS Docket Clerk
Docket #03-025IF
Room 102, Cotton Annex
300 12th and C Street, SW
Washington, DC 20250-3700

627

RE: Docket #03-025IF, Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle

To Whom It May Concern:

I am submitting these comments on behalf of Farm Sanctuary and its 100,000 members regarding USDA's interim final rule on the Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Livestock.

Farm Sanctuary strongly supports the USDA's prohibition of the use of all non-ambulatory cattle in the human food supply. We urge the USDA to broaden this prohibition to include all species of non-ambulatory livestock and to require that all non-ambulatory animals be euthanized immediately upon arrival at federally inspected slaughter facilities. We also encourage the USDA to pursue a ban on the movement of disabled livestock off the farm. Finally, Farm Sanctuary supports the proposed prohibition of the use of "specified risk materials" (SRMs) for food and recommends that all of the intestines of cattle be included in the ban and that the ban be extended to SRMs from animals of all ages, not just those 30 months and older. The rationale for these recommendations is described below.

1. All non-ambulatory cattle should be excluded from the food supply.

The *Federal Register* notice announcing the interim final rule excluding non-ambulatory, or "downed," animals from the food supply offers justification for the ban:

- BSE has been found to be more common in downed than healthy cattle. In BSE testing conducted in Germany in 2001, positive samples were detected in 0.48 percent of sick cows, compared with 0.02 percent of dead cows, and 0.002 percent of normal cows.

- Government slaughterhouse veterinarians are often unable to determine by visual examination whether an animal is safe to be slaughtered. Conditions that present the most serious risk to public health – namely, bacterial contamination and central nervous system disorders like BSE – are difficult to diagnosis solely on the basis of a cursory physical examination. The signs of BSE often cannot be differentiated from the signs of the many other diseases and conditions affecting downer cattle. A risk assessment on the potential for BSE in the U.S. conducted by the Harvard Center for Risk Analysis estimated that up to 50 percent of BSE cases could be missed on ante-mortem inspection at slaughter.
- Testing every downed animal will not necessarily provide adequate protection against BSE because it is possible that a different variant of the disease is currently present – or at some point may be present – in the U.S. Individual laboratory tests have failed to detect the disease under certain circumstances. For example, the laboratory test currently employed by the USDA failed to detect the disease when used recently by authorities in Japan.

While the stated objective of the interim final rule is to minimize human exposure to materials that contain the BSE agent, prohibiting downed animals from the food supply will also safeguard against other foodborne disease, drug residues, and bio-terrorism.

Foodborne Disease

According to the United States Centers for Disease Control and Prevention (CDC), the foods most often associated with foodborne illness are raw foods of animal origin, including meat and poultry. Although more than 250 different foodborne diseases have been described, the CDC identifies the most common foodborne infections as those caused by the bacteria *Campylobacter*, *Salmonella*, and *Escherichia coli* (*E. coli*). Another foodborne pathogen, *Listeria*, is less common but highly virulent, causing approximately 500 deaths per year in the U.S. These 4 pathogens are, in fact, the foodborne bacteria most commonly found in dairy cattle, and represent the most significant biological risks associated with the slaughter of cull dairy cattle, including downer animals.

In 1999, the CDC conducted an extensive study of the impact of foodborne diseases on health in the United States. The study concluded that each year in the U.S. foodborne disease is responsible for approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths (*Emerging Infectious Diseases*; 1999;5:607). In 2002, FSIS issued 80 recalls for possible bacterial contamination of meat and poultry. A total of 56 million pounds was recalled, enough to serve a potentially tainted burger or chicken patty to every man, woman, and child in America.

Epidemiological research has documented an increase in the prevalence of 2 of these foodborne pathogens – *E. coli* and *Salmonella* – among downed animals.

E. coli –

There are several disease-causing strains of *E. coli*, including 0157:H7, which infects humans through the consumption of food or water that has been contaminated with cow feces. Both *E. coli* 0157:H7 and non-0157:H7 strains have been found to be prevalent in the feces, hides, and carcasses of cattle. In one study, 28 percent of cattle at meat processing plants in the Midwestern U.S. tested positive for *E. coli* 0157:H7. When the animals in this study were followed through slaughter, 43 percent of the carcasses sampled pre-evisceration contained *E. coli* 0157:H7 contamination (*Proceedings of the National Academy of Science*;2000;97:2999). In another study, 54 percent of carcasses at 4 large cattle slaughter plants were found to harbor non-0157:H7 *E. coli* (*Applied and Environmental Microbiology*;2002;68:4847). Not only has *E. coli* been shown to be prevalent in cattle, it has been found to be more common in non-ambulatory versus healthy cows. A study conducted at 2 Wisconsin slaughter facilities in 2001 tested fecal and/or tissue samples from the intact colons of 203 downer dairy cattle and 201 healthy dairy cattle. The research documented a 3.3-fold-higher prevalence of *E. coli* 0157:H7 in the downer cows (*Applied and Environmental Microbiology*;2003;69: 4683).

Salmonella –

The Salmonella pathogen has also been associated with downed dairy cows. Dr. Carolyn Stull of the University of California-Davis conducted a study of disabled cows at 2 commercial slaughter facilities near San Bernardino County's Dairy Preserve in southern California in the mid-1990s. Rumen samples collected from 6 of 20 downers (or 12 percent) tested positive for Salmonella. One of the Salmonella-positive animals was reported by the researcher to have septicemia (bacterial toxins in the blood); yet, the slaughterhouse inspector, apparently unaware of the condition, passed the animal for human consumption.

Outbreaks of Salmonella Newport, a strain of Salmonella resistant to antibiotics, have been traced back to meat produced from slaughtered dairy cows and to processing plants that slaughter a higher proportion of downed animals. In 1985, the Los Angeles County Health Department studied an outbreak of Salmonella Newport that infected 298 people, 2 of whom died. The Department identified hamburger from slaughtered dairy cows as the vehicle of transmission and traced the strain back to the dairy farms of origin. It also traced the epidemic strain to individual slaughter plants and documented a positive correlation between carcass contamination rates and rates of condemnation of moribund and dead animals at slaughter facilities, suggesting that the plants with Salmonella contamination were those receiving and accepting a higher proportion of sick animals (*New England Journal of Medicine*;1987;316:565). During 2001-2002, health departments in several states documented an association between an increase in Salmonella Newport infections and exposure to dairy farms and ill cattle. In one outbreak, the source of infection was identified as ground beef, most likely from slaughtered dairy cows (*Journal of the American Medical Association*;2002; 288:951).

Anthrax –

Although not a common foodborne disease in the U.S., human cases of Anthrax (caused by the pathogen *Bacillus anthracis*) may number in the thousands worldwide every year. People may contract the disease by several routes, including ingesting meat from infected animals. During the summer of 2000, 53 farms in North Dakota reported Anthrax

infections that killed a total of 180 animals. A North Dakota farmer disposing of animals who had died during the outbreak developed cutaneous Anthrax. That summer, 6 additional people were exposed to the disease when a Minnesota farmer killed a downed cow, had the meat processed by a custom slaughter plant and fed it to his family. Fortunately, laboratory samples from the downed animal identified the disease, and the family was treated early enough to prevent serious illness or death.

Drug Residue

Another concern associated with the slaughter of downed animals is the possible presence of drug residues in the carcass. When an animal goes down on the farm, she may receive medical treatment by the farmer or a veterinarian, which may include the administration of antibiotics and other drugs. If it is determined that recovery is unlikely, the animal may be transported to market or slaughter in order to receive some salvage value from the animal. In this case, insufficient time may have elapsed for drug withdrawal, and residue may be still present when the animal is slaughtered and the meat processed for human food. It has also been suggested that the metabolism of downed animals may be slower than that of healthy animals, and this would necessitate a longer withdrawal time for drugs to be processed and removed by the animal's system.

Bio-terrorism

Concerns about the possibility of a bio-terror attack on U.S. domestic agriculture have led to calls for increased security in our food system. Zoonotic outbreaks, such as foot-and-mouth disease in cattle and exotic Newcastle disease in poultry, can result in the death or destruction of millions of animals. In addition, bacterial or viral pathogens, such as Anthrax, would be capable of sickening or killing thousands – if not millions – of Americans if the agents were to be released in the public meat supply. Of particular concern is the vulnerability of cull dairy cows to contamination, since these animals are the source of most hamburger products consumed in this country. Because the meat from many animals is mixed together for grinding, a single downed dairy cow infected with a bacterial agent can contaminate 32,000 pounds of ground beef (*Epidemiologic Reviews*; 1996;18:29).

Many in the meat industry are not opposed to ending commerce in downers because they recognize that such a move would have little economic impact on farmers. According to an article in *Dairy Herd Management*, cull cow sales account for only 4 percent of the annual income of dairies. In studying the slaughter of downers in California, Dr. Pam Hullinger of the California Department of Food and Agriculture found that, on average, only \$28.70 profit was realized from the sale of each downer dairy cow. Not only are revenues due to the sale of downers minimal, there are costs involved. Losses associated with the additional handling required by disabled cows equaled \$0.56 for every cow and bull marketed in 1999, or approximately \$15 million for the industry as a whole (*Journal of Animal Science*;2001;79(E. Suppl.):E166).

2. Prohibition on downers should be extended to all livestock.

The *Federal Register* notice announcing the interim final rule on meat produced by advanced meat recovery (AMR) systems notes that the presence of CNS-type tissues in pork product recovered from AMR systems may be a concern. As a result, the requirements included in the interim final rule are being made applicable to products derived from pork bones. This acknowledges a possible risk posed by meat products from animals other than cattle. In fact, it has been known since the 1940's that sheep in the U.S. harbor "scrapie," a form of transmissible spongiform encephalopathy (TSE). In addition, there are reports of pigs harboring an apparent TSE at an Albany, NY slaughterhouse in the 1980's.

To date, TSE surveillance efforts in the U.S. have been woefully inadequate. We have failed to test an appropriate number of animals to determine the extent to which U.S. livestock species may be infected. Disease detection and control efforts are further hindered by our limited understanding of these diseases in cattle and other species. As the proposed rule acknowledges, "The agent that causes BSE and other TSEs has yet to be fully characterized," and, "Available data on the development and distribution of tissue infectivity in BSE infected cattle are incomplete." We believe that mad cow disease has likely been spreading in the U.S. for at least a decade. This concern is consistent with the conclusion that we have indigenously infected animals in the U.S. that was made by the USDA Secretary's Foreign Animal and Poultry Disease Advisory Committee's Subcommittee on the United States' Response to the Detection of a Case of Bovine Spongiform Encephalopathy in February 2004.

Multiple variations of BSE likely exist, as illustrated by the finding in October 2003 of a 23-month-old bull with BSE in Japan. Not only was it assumed that animals less than 30 months of age presented little or no risk of harboring the disease, but, according to USDA, "the form of the BSE agent found in the animal was atypical." In November 2003 Japan found BSE in a 21-month old animal. Two of the nine confirmed cases of BSE in Japan have been found in animals less than 24 months old. USDA reports, "Like the 23-month old animal, this animal apparently did not have clinical signs of the disease. However, the abnormal prion protein detected in this animal does not appear to be the same as the apparently atypical form detected in the 23-month-old animal."

We believe it is probable that in addition to the BSE variant recently discovered in a cow in Washington state, there are likely other variants of BSE afflicting cattle, and other poorly understood or unidentified TSE variants affecting other livestock species. And we are concerned that such agents have been present in the U.S. livestock population for at least a decade. Research published by Dr. Richard Marsh in 1993 suggested "the presence of an unrecognized BSE-like disease in the United States," while a 1994 article published by R.C. Cutlip et al in the *Journal of Infectious Diseases* (1994;169:814) suggested that the agent causing scrapie in sheep could cause neurological disease in cattle. The abstract states:

"To determine if sheep scrapie agent(s) in the United States would induce a disease in cattle resembling bovine spongiform encephalopathy, 18 newborn

calves were inoculated intracerebrally with a pooled suspension of brain from 9 sheep with scrapie. Half of the calves were euthanized 1 year after inoculation. All calves kept longer than 1 year became severely lethargic and demonstrated clinical signs of motor neuron dysfunction that were manifest as progressive stiffness, posterior paresis, general weakness, and permanent recumbancy. The incubation period was 14-18 months, and the clinical course was 1-5 months. The brain from each calf was examined for lesions and for protease-resistant prion protein. Lesions were subtle, but a disease specific isoform of the prion protein was present in the brain of all calves. Neither signs nor lesions were characteristic of those for bovine spongiform encephalopathy."

Variants of BSE or other TSEs may be linked to cases of classical or the "sporadic" form of Creutzfeldt-Jakob Disease (CJD) in the U.S. and elsewhere. A study by French scientists, published in 2001 (*Proceedings of the National Academy of Sciences*; 2001;98:4142), found a strain of scrapie also caused brain damage in mice similar to the classical form of CJD. In another study conducted in Great Britain, scientists injected BSE into mice whose brains had been genetically engineered with human genes. One group of mice became ill with the human form of mad cow, referred to as the new variant CJD. These two studies suggest that some of the hundreds of Americans who contract classical CJD each year could have been infected by BSE or TSE-infected meat.

Britain's Department for Environment, Food and Rural Affairs announced recently that it had found "a type of scrapie not previously seen in the UK" (NewScientist.com News Service, April 8, 2004). For the first time, a sheep with scrapie symptoms has given laboratory test results that resemble BSE. Scientists with the agency say they cannot rule out the possibility that the finding indicates the existence of a new form of BSE adapted to sheep. In cattle, prion diseases are not known to be spread between animals, so that, at least theoretically, the risk of BSE transmission would eventually die out as a result of prohibitions on animal-derived feed. With sheep, however, prion diseases can be transmitted from animal to animal and, as a result, a form of BSE acquired from cattle prior to the feed bans could still be circulating. TSEs in sheep may actually present a greater risk to humans than BSE in cattle because sheep carry prions in more tissues including the muscle of the animal which is consumed as meat.

The *Federal Register* notice announcing the interim final rule also mentions that an atypical form of the BSE agent has recently been identified in Italy. In a published report entitled "Identification of a second bovine amyloidic spongiform encephalopathy: Molecular similarities with sporadic Creutzfeldt-Jakob disease" (*Proceedings of the National Academy of Sciences*; 2004; 101: 3065) the authors state:

"The unprecedented biological properties of the BSE agent, which circumvents the so-called 'species barrier' between cattle and humans and adapts to different mammalian species, has raised considerable concern for human health. To date, it is unknown whether more than one strain might be responsible for cattle TSE or whether the BSE agent undergoes phenotypic variation after natural transmission. Here we provide evidence of a second cattle TSE. The disorder was pathologically characterized by the

presence of a PrP-immunopositive amyloid plaques, as opposed to the lack of amyloid deposition in typical BSE cases, and by a different pattern of regional distribution and topology of brain PrPSc accumulation. In addition, Western blot analysis showed a PrPSc type with predominance of the low molecular mass glycoform and a protease-resistant fragment of lower molecular mass than BSE-PrPSc. Strikingly, the molecular signature of this previously undescribed bovine PrPSc was similar to the encountered in a distinct subtype of sporadic Creutzfeldt-Jakob disease.”

It is possible that some cases of CJD or other human neurological diseases in the U.S. are caused by eating meat from sheep and pigs. Scrapie presents an ongoing problem in the U.S., with hundreds of cases confirmed in 2003. Speculation exists that pigs may also harbor mad cow disease and pass it on to humans. It is known that pigs are susceptible to the disease; research has shown that pigs can be infected by mad cow brains (*Veterinary Record*; 1990;127:338). Epidemiological studies have also suggested a link between sporadic CJD and pork consumption. One study (*American Journal of Epidemiology*; 1985;122:443) analyzed peoples’ diet histories and found that those who included ham in their diet appeared 10 times more likely to develop CJD than those who didn’t eat ham. The researchers concluded, “The present study indicated that consumption of pork as well as its processed products (e.g., ham, scrapple) may be considered as risk factors in the development of Creutzfeldt-Jakob disease.”

An article published in the *National Hog Farmer* in February 2002 estimated the number of crippled hogs presented at slaughter in the U.S. as 420,000/year. If pigs do in fact harbor a TSE, these disabled animals represent those at highest risk for transmitting the disease to people. Given the research suggesting a link between TSEs in animals other than cattle and cases of CJD in humans, it appears prudent to prohibit the slaughter of all non-ambulatory animals, not just cattle.

3. Downed animals should be euthanized immediately upon arrival at a slaughter facility.

The *Federal Register* notice announcing the interim final rule states that if an animal becomes non-ambulatory in route to the slaughter plant or on the premises of the establishment the animal is required to be humanely euthanized. However, an FSIS Notice issued January 12, 2004 in conjunction with the interim final rule entitled “Interim Guidance for Non-Ambulatory Disabled Cattle and Age Determination” states that, at the request of the owner or operator, condemned downer animals “can be set apart and held for treatment,” or may be released after permission for the movement of such livestock from the establishment premises is obtained.

Non-ambulatory animals should be euthanized immediately, failure to do so is unacceptable from both an animal welfare and a public health perspective. It is the position of the American Veterinary Medical Association that “if an animal is down at a terminal market (e.g., slaughterhouse or packing plant), the animal should be euthanized immediately.” The FSIS Notice suggests that it would be acceptable to remove a downer cow from the premises and, if the animal becomes ambulatory again, resubmit the animal

for slaughter. The FSIS Notice cites 9 CFR 309.13 (“Disposition of condemned livestock”), which does in fact allow for condemned animals to be set apart and treated, and to be released from the slaughter plant premises if permission is obtained. The interim final rule should be changed to amend 9 CFR 309.13 to require that all non-ambulatory animals are euthanized immediately.

4. Transport of downed animals from the farm should be prohibited.

In January 2003, the USDA Animal and Plant Health Inspection Service released an Advance Notice of Proposed Rulemaking, “Risk Reduction Strategies for Potential BSE Pathways Involving Downer Cattle and Dead Stock of Cattle and Other Species” (*Federal Register*;68:2703). In the Notice, APHIS raised the possibility of banning the movement off the farm of non-ambulatory animals in order to decrease the risk of BSE transmission.

Although the slaughter of non-ambulatory cattle is now to be prohibited, it is possible some farmers may still attempt to transport downers to other farming operations, to auction or slaughter. Farm Sanctuary encourages the USDA to continue to pursue a ban on the transport of non-ambulatory animals. The following arguments are offered in support of this position:

- Downed animals spread foodborne bacteria. The California Dairy Quality Assurance Program notes that the highest bacterial levels are found in cull dairy cows getting ready to go to slaughter. Transportation increases the shedding of these pathogens in the manure of sick animals, and other animals’ hides may become contaminated by this manure, providing an important method of entry for pathogens into a slaughter plant. Therefore, to reduce the risk of foodborne illness, the Program recommends that sick cows not be sent to slaughter.
- Handling and transportation are known to be significant sources of stress. In conducting research on the handling of non-ambulatory cows at slaughter plants, Dr. Stull of the University of California-Davis found that levels of 2 stress indicators – acute phase protein and cortisol – in downed cows were double and triple, respectively, the levels for normal cattle. She concluded that the cows had “experienced severe stress, probably due to their non-ambulatory condition.”
- Due to their size and weight, it is very difficult to move a downed cow humanely. Non-ambulatory animals are frequently subjected to unnecessary pain and distress during movement from one location to another. This mistreatment often results in injuries ranging from bruises and abrasions to broken bones and torn ligaments. While specific devices have been designed to move non-ambulatory animals, many establishments do not have this equipment available.
- Downed animals at stockyards rarely receive veterinary attention. Stockyards are reluctant to call veterinarians because they do not own the animals, and don’t want to be financially responsible for services rendered. Because downers are

immobile, they cannot get to food and water. They may lie for hours or even days without having their most basic needs met, and many die of gross neglect.

- Prohibiting the transport and marketing of non-ambulatory animals provides an economic incentive for better animal handling. Animal handling expert, Dr. Temple Grandin, has estimated that up to 90 percent of downers are preventable through improved animal husbandry.
- A number of meat industry groups, including the American Farm Bureau, the American Meat Institute, the National Cattlemen's Beef Association, and the National Pork Producers Council, have recommended that non-ambulatory animals be euthanized on the farm and not transported.

5. SRMs should include all of the intestines, and SRMs from animals of all ages should be excluded from the food supply.

The interim final rule prohibits the tonsils and the distal ileum of the small intestine of all cattle from human food. However, the European Union has identified the entire intestine, from duodenum to rectum, as specified risk material and prohibits its inclusion in the food supply of member nations (*Journal of the European Communities*, December 2000). According to the Scientific Steering Committee of the European Union, the intestine should be considered a primary source of infectivity since infection with BSE has come from cattle ingesting contaminated feed. In addition, in classifying the entire intestine as SRM, the EU Steering Committee notes that because slaughterhouse contamination of other intestinal areas with matter from the ileum can't be avoided, it is prudent to remove the entire small and large intestine.

The interim final rule also prohibits the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (with exceptions), and the dorsal root ganglia of cattle 30 months of age and older from human food. However, because only about 15 percent of cattle slaughtered in the U.S. are over 30 months of age, this will allow the brains and other central nervous tissue from 30 million animals a year to enter into the human food supply.

The *Federal Register* notice announcing the interim final rule notes that the age at which cattle develop clinical BSE varies and that the "lower ranges of this age distribution includes some cattle younger than 30 months of age." As mentioned previously, 2 of the 9 confirmed cases of BSE in Japan have occurred in animals under 30 months of age. The international panel convened by Agriculture Secretary Veneman to evaluate the nation's BSE safeguards recommended that the U.S. ban on SRM should be extended to cattle a year old or older. "A cutoff of 12 months represents a recognition of the fact that some cattle under 30 months of age may be slaughtered with infectivity present," the report notes.

Farm Sanctuary believes that a total ban on SRM, regardless of age of the animal, would best protect the public since a blanket ban would significantly improve enforcement of

the prohibition and eliminate the need to determine the age of each animal. We support the development of a national animal identification and tracking system; however, none exists at present. Until such a system is fully implemented, FSIS personnel will be responsible for reviewing the records of each animal arriving for slaughter. If the appropriate records are unavailable or unreliable, FSIS veterinary medical officers will be required to make a physical assessment to determine age. Such an assessment is somewhat subjective and subject to error. Even with an animal identification system, errors are possible. Furthermore, it is more efficient to process all carcasses in a similar manner than identifying and segregating parts coming from animals of a certain age. Therefore, we recommend that SRMs from animals of all ages be excluded from the human food supply.


Conclusion

Farm Sanctuary strongly supports the prohibition on all non-ambulatory cattle in the food supply and requests that the prohibition be extended to all livestock, not just cattle. To provide for animal welfare, as well as to safeguard public health, we urge that the regulation regarding the disposition of condemned livestock (9 CFR 309.13) be amended to require immediate euthanasia of all non-ambulatory animals at USDA inspected slaughterhouses. We also encourage the USDA to pursue a prohibition on the movement of non-ambulatory animals from the farm, as we believe such a measure would further protect the public from foodborne disease and also provide an incentive for better animal husbandry. Dr. Temple Grandin has estimated that around 90% of downed animals can be prevented with improved care.

As in the case of downed animals and BSE, there is often a connection between the treatment of animals and public health. While Farm Sanctuary is pleased the USDA has taken action to end the slaughter of non-ambulatory cattle for human food, we believe that additional measures are necessary to minimize both the suffering of farm animals and the risk they pose to the public.

Thank you for allowing Farm Sanctuary the opportunity to comment on a matter of great importance to our members.

Sincerely,


Gene Bauston, President
Farm Sanctuary