

OFFICERS

David O. Wiebers, M.D.
Chair of the Board
Anita W. Coupe, Esq.
Vice Chair

Wayne Pacelle
President & CEO

G. Thomas Waite III
Treasurer & CFO

Roger A. Kindler, Esq.
General Counsel & Vice President

STAFF VICE PRESIDENTS

Andrew N. Rowan, Ph.D.
Executive Vice President Operations

Patricia A. Forkan
Senior Vice President International Programs & Regions

Martha C. Armstrong
Senior Vice President Domestic Animal Programs

John W. Grandy, Ph.D.
Senior Vice President Wildlife & Habitat Protection

Michael C. Appleby, B.Sc., Ph.D.
Farm Animals & Sustainable Agriculture

Katherine Benedict
Administration, Information Services, & Technology

Nicholas Braden
Communications

Richard M. Clugston, Ph.D.
Higher Education

Randall Lockwood, Ph.D.
Research & Educational Outreach

Steve Putnam
Business Development & Corporate Relations

Robert G. Roop, Ph.D., SPHR
Human Resources & Education Programs

Melissa Seide Rubin, Esq.
Field & Disaster Services

Martin L. Stephens, Ph.D.
Animal Research Issues

Richard W. Swain Jr.
Investigative Services

Gretchen Wyler
Hollywood Office

DIRECTORS

Leslie Lee Alexander
Patricia Mares Asip

Peter A. Bender
Donald W. Cashen, Ph.D.

Anita W. Coupe, Esq.
Judi Friedman

Alice R. Garey
David John Jhirad, Ph.D.

Jennifer Leaning, M.D.
Eugene W. Lorenz

William F. Mancuso
Patrick L. McDonnell

Judy J. Pell
Joe Ramsay, Esq.

Jeffery D. Rose
James D. Ross, Esq.

Manlyn G. Seyler
Walter J. Stewart, Esq.

John E. Taff
David O. Wiebers, M.D.

K. William Wiseman

John A. Hoyt
Paul G. Irwin

Presidents Emeriti

Murdaugh Stuart Madden, Esq.
Vice President & Senior Counsel

NGO in general consultative status with the Economic and Social Council of the United Nations

October 12, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Docket No. 2004N-0081, "Use of Materials Derived from Cattle in Human Food and Cosmetics"

On behalf of The Humane Society of the United States (HSUS) and the more than 8 million supporters of our organization nationwide, we would like to take this opportunity to submit comments regarding the Interim final rule "Use of Materials Derived from Cattle in Human Food and Cosmetics." One of the most prudent measures taken by the United States Department of Agriculture (USDA) to mitigate bovine spongiform encephalopathy (BSE) risks was the banning of all non-ambulatory disabled cattle (downers) from the human food supply. The HSUS strongly supports this policy as it helps to protect animal welfare and the safety of the food supply. We therefore strongly urge the Food and Drug Administration (FDA) to extend the prohibition on non-ambulatory disabled cattle to all the human food and cosmetics under its regulation.

Animal Welfare

Downed animals suffer terribly. Firstly, they suffer as a result of the illness and or injury that incapacitates them. A study on disabled cattle found their cortisol levels (a physiological indicator of stress) were nearly triple that of normal healthy cattle.¹ The researchers concluded that the cows were suffering from severe stress. Furthermore, because they need special processing, downed animals may be left in this condition for hours or days without food, water, or veterinary care as they await slaughter.

Transporting downers in inhumane ways compounds this suffering. Non-ambulatory disabled animals are difficult, if not impossible, to transport humanely. Investigations by The HSUS and other animal protection organizations have revealed that animals too sick or injured to stand or walk are routinely kicked, dragged with chains, shocked with electric prods, and pushed by bulldozers in efforts to move them at auction and slaughter facilities. A national study by industry expert Temple Grandin, Ph.D., found that at some plants the most common handling problem associated with downers was dragging them while they were conscious.²

Some animals may be non-ambulatory due to broken legs. Anyone who has broken a bone knows the need for handling with the utmost care to minimize pain. To be dragged by chains, and perhaps even pulled by the very limb that is broken, is abhorrently cruel. As Dr. Grandin has also noted, "Ninety percent of all downers are preventable."³ It is precisely the cases that involve broken bones and other injuries that are the most preventable with improved animal husbandry and handling practices. Prohibiting use of these animals for human food will encourage greater care to keep them from becoming downers in the first place.

Food Safety

Allowing downers to be processed for human food threatens the safety of the food supply. Non-ambulatory disabled cattle are understood to be at heightened risk for BSE. A Swiss study (one of several cited by USDA) found that downer cattle are 49 to 58 times more likely to have BSE than cattle identified through passive surveillance (i.e., those reported to veterinary authorities as BSE-suspect based on clinical observation).^{4,5} Given the terrible and devastating nature of new variant Creutzfeldt-Jakob disease (vCJD) in humans, thought to be caused by eating meat contaminated with the abnormal prions that cause BSE, keeping downer cattle out of the U.S. food supply makes eminent sense.

Animals unable to stand or walk are not only at a higher risk of suffering from BSE but also have been shown to have a higher prevalence of *Escherichia coli*, *Salmonella*, and other dangerous pathogens that can transmit disease to consumers. In particular *E. coli* O157: H7 is a significant public health concern because it has been implicated in more than 70,000 human infections and around 61 human deaths each year in the U.S.^{6,7} Cattle are the primary reservoir for *E. coli* O157:H7⁸ and a study on the subject found downer cattle were more than 3 times more likely to have this deadly pathogen than healthy cattle.⁹ Downer cows can also shed more salmonella.¹⁰

Public Support

When the USDA announced its interim ruling prohibiting the processing of non-ambulatory disabled cattle for the human food supply, there was an outpouring of public support. Major retailers, consumer groups and other nonprofits, and some agricultural organizations and individual ranchers expressed strong support for the ban as well. In fact, of approximately 22,000 comments submitted to the USDA, more than 99 percent strongly support the ban. Details on this and more are included in the linked HSUS report “[Public Comments on USDA’s Downed Animal Ban: Major Retailers and the Vast Majority of Americans Support No-Downer Policy; Some Industry Groups Reverse Their Support for the Ban](#)”. The massive support for the ban was not only based on food safety concerns but also humane concerns, and is in line with a 2003 Zogby poll that showed a majority of Americans oppose the use of downed animals for human food. According to that poll, more than three-fourths of the U.S. population feels it is unacceptable to use downed animals for human consumption (77%). An even larger majority of the U.S. population is concerned that sending downed animals to slaughterhouses could put human consumers at risk for mad cow disease (81%).¹¹ The FDA should heed this strong and unwavering support for the prohibition on non-ambulatory disabled cattle and extend the ban to the human food and cosmetics it oversees.

In conclusion, we urge the FDA to prohibit the use of non-ambulatory disabled cattle in the human food and cosmetics under its regulation. Animals that are unable to stand and walk are suffering and their meat and meat byproducts should be entirely kept out of the food supply. Thank you for your time and consideration.

Sincerely,

Wayne Pacelle
President and CEO

References:

1. LCI Annual Meeting Proceedings. 1996. Website:
<http://www.animalagriculture.org/Proceedings/1996AMProceedings.asp>
Accessed August 2004
2. Grandin T. 1998. Handling of Crippled and Nonambulatory Livestock. *Animal Welfare Information Center Bulletin* . Volume 9, Number 1/2, Fall 1998
3. Grandin T. 1991. Pro-active activism. *Meat & Poultry*. August 1991
4. Doherr MG, Heim D, Fatzer R, Cohen CH, Vandevelde M, and A Zurbriggen. 2001. Targeted screening of high-risk cattle populations for BSE to augment mandatory reporting of clinical suspects. *Prev Vet Med*. 2001. 51(1-2):3-16
5. Food Safety and Inspection Service, USDA. 2004. Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle. *Federal Register* 69(7)1862-1874
6. Byrne CM, Erol I, Call JE, Kaspar CW, Buege DR, Hiemke CJ, Fedorka-Cray PJ, Benson AK, Wallace FM, and JB Luchansky. 2003. Characterization of Escherichia coli O157:H7 from downer and healthy dairy cattle in the upper Midwest region of the United States. *Appl Environ Microbiol*. 2003 Aug;69(8):4683-8
7. Kassenborg HD, Hedberg CW, Hoekstra M, Evans MC, Chin AE, Marcus R, Vugia DJ, Smith K, Ahuja SD, Slutsker L, Griffin PM, and Emerging Infections Program FoodNet Working Group. 2004. Farm visits and undercooked hamburgers as major risk factors for sporadic Escherichia coli O157:H7 infection: data from a case-control study in 5 FoodNet sites. *Clin Infect Dis*. 2004 Apr 15;38 Suppl 3:S271-8
8. *Id*
9. Byrne CM, Erol I, Call JE, Kaspar CW, Buege DR, Hiemke CJ, Fedorka-Cray PJ, Benson AK, Wallace FM, and JB Luchansky. 2003. Characterization of Escherichia coli O157:H7 from downer and healthy dairy cattle in the upper Midwest region of the United States. *Appl Environ Microbiol*. 2003 Aug;69(8):4683-8
10. New York State Cattle Health Assurance Program. 2002. Website:
<http://nyschap.vet.cornell.edu/module/salmonella/section2/SalmonellaRiskAssessment.pdf> Accessed August 2004
11. Zogby International. 2003. Results from Zogby America Poll. Zogby, New York