



Consumer Federation of America

October 25, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-D-0378

To Whom It May Concern:

The Consumer Federation of America (CFA) appreciates the opportunity to respond to the Food and Drug Administration's (FDA) request for comments on its Draft Compliance Policy Guide for *Salmonella* in Animal Feed (**Docket No. FDA-2010-D-0378**).

CFA is a non-profit association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions and food safety organizations. CFA's Food Policy Institute was created in 1999 and engages in research, education and advocacy on food safety, food and agricultural policy, agricultural biotechnology, and nutrition.

Salmonella is an important public health problem. The Centers for Disease Control and Prevention (CDC) report that approximately 40,000 cases of salmonellosis occur in the United States every year, and the actual number of illnesses may be thirty or more times greater due to lack of diagnosis or inadequate reporting. A *Salmonella* infection typically causes symptoms of diarrhea, fever and abdominal cramps and can result in death in some persons. The elderly, children and persons with compromised immune systems are especially at risk for severe illness. Salmonellosis can also result in long-term health complications such as Reiter's syndrome which can result in chronic arthritis¹.

All Animal Feed Contaminated with *Salmonella* Should be Considered Adulterated
CFA strongly supports the regulation of *Salmonella* in animal feed products, as addressed by FDA Compliance Policy Guide Section 555.300 Foods, Except Dairy Products -

¹ Centers for Disease Control and Prevention, *Salmonella* General Information (Sept. 27, 2010), <http://www.cdc.gov/salmonella/general/index.html>.

Adulteration with *Salmonella* (CPG 555.300)². Under CPG 555.300 feed contaminated with *Salmonella* is considered adulterated and is subject to seizure or detention. FDA's draft CPG would substantially weaken this current safety standard by limiting action on *Salmonella*-contaminated feed. This runs contrary to a preventive, public health-based approach to food and feed safety. CFA opposes this change and urges the agency to maintain the current CPG.

Animal feed that may be contaminated with *Salmonella* and that does not undergo a commercial step to effectively kill the microbe can pose a significant risk to public health. Animal feed or pet food contaminated with *Salmonella* can cause salmonellosis in humans via direct handling of the contaminated feed or handling of an animal or pet that has consumed the contaminated feed. Animals can often be asymptomatic carriers of *Salmonella*. Bacteria that may cause human infection without displaying illness in animals can be readily transmitted to animals through feed and can be found on animal carcasses used for human food³.

Because of the close contact that humans share with their pets, domesticated animals are potential sources of numerous zoonotic diseases, including salmonellosis⁴. Young children, who can accidentally ingest pet food and who come in close contact with pets, are at particular risk. The risk for contracting salmonellosis from contaminated animal feed is not limited to household members. Dogs and cats are used for therapeutic visits to hospitals and elderly care facilities, where the *Salmonella* organism may be passed on to those individuals. This is concerning as the elderly are one of the most at-risk populations for foodborne illness. Because of these implications, domesticated animals consuming *Salmonella*-contaminated feed pose a risk to human health. Consequently, all feed contaminated with any *Salmonella* serotype that comes into contact with humans should be considered adulterated.

However, CFA does not agree with FDA's draft CPG that proposes to limit action for other animal feed to only *Salmonella* serotypes pathogenic to animals. FDA has provided no evidence that limiting action to *Salmonella* serotypes of animal concern is sufficient to protect the public health. In addition, it is unclear how FDA would even determine in a timely manner which *Salmonella* serotype has contaminated animal feed.

The science surrounding *Salmonella* is continually changing. Information on *Salmonella* is constantly being revised and future studies and outbreaks may update what we currently know about *Salmonella*. Some serotypes may not be identified as causing human illness today, but may be linked to human illness in the future. While today the top serotypes that account for approximately half of *Salmonella* reports are Enteritidis,

² U.S. Food and Drug Administration, CPG Sec. 555.300 Foods, Except Dairy Products – Adulteration with *Salmonella* (December 9, 2009), <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074553.htm>.

³ Crump, John A., et. al., *Bacterial Contamination of Animal Feed and Its Relationship to Human Foodborne Illness*, Food Safety (2002) 859-865.

⁴ Finley, Rita, et. al., *Human Health Implications of Salmonella-Contaminated Natural Pet Treats and Raw Pet Food*, Food Safety (2006) 686-691.

Typhimurium and Newport, the main serotypes reported between 1968 and 1979 were Typhimurium, Typhi, Heidelberg and Enteritidis^{5,6}.

A further complication is the difficulty of linking contaminated feed directly to human illnesses. Public health investigations do not usually trace the source of contamination completely through the food chain to the initial farm and the animal feed. Further, surveillance of animal feed for bacterial contamination is not adequately developed and it is not correlated with human illness data and surveillance data from food-producing animals in order to link outbreaks of human illness to contaminated animal feed⁷. As a result, the risk of contaminated feed to human health is likely underestimated and our knowledge about which *Salmonella* serotypes cause human illness incomplete. In order to avoid any unintended negative consequences to public health, FDA should not limit action to a narrow set of *Salmonella* serotypes.

Animal Feed Must be Monitored to Ensure the Absence of *Salmonella*

Effective oversight of animal feed to reduce the risk of contamination from pathogens such as *Salmonella* is important. The Government Accountability Office (GAO) and others have repeatedly questioned the ability of federal agencies to adequately assure the safe production of animal feed. As GAO reported, “Studies by USDA and others have found *Salmonella* in animal feed, and CDC has stated that sensitive testing methods may show that the magnitude of contamination in some animal feeds may be extremely high⁸.”

While the focus of these comments is on *Salmonella* in animal feed, FDA’s oversight of other animal feed issues is relevant and raises questions about the agency’s ability to properly oversee the safety of animal feed. In its review of government measures to prevent the spread of Bovine Spongiform Encephalopathy (BSE), GAO identified specific problems with FDA’s oversight of animal feed, which can serve as a main vector for the spread of the disease. FDA’s 1997 feed ban rule (updated in 2008) was intended to prohibit most mammalian protein in feed for ruminants to prevent the spread of BSE through animal feed⁹. However, loopholes remain in the FDA’s feed ban. FDA still allows poultry litter to be used as cattle feed, a practice that the Food Animal Concerns Trust (FACT) has petitioned the FDA to ban as the feed may contain ingredients that can cause BSE¹⁰. Further, GAO identified important gaps in FDA’s oversight of animal feed

⁵ Centers for Disease Control and Prevention, *Salmonella*: Technical Information (September 27, 2010), <http://www.cdc.gov/salmonella/general/technical.html>.

⁶ Blaser, Martin J. and Roger A. Feldman, *Salmonella Bacteremia: Reports to the Centers for Disease Control, 1968-1979*, The Journal of Infectious Diseases (1981) 743-746.

⁷ Crump, John A., et. al., *Bacterial Contamination of Animal Feed and Its Relationship to Human Foodborne Illness*, Food Safety (2002) 859-865.

⁸ United States General Accounting Office, *Food Safety: Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed*, (2000) 9.

⁹ U.S. Food and Drug Administration, Animal and Veterinary: Bovine Spongiform Encephalopathy (April 26, 2010),

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/default.htm>.

¹⁰ Food Animal Concerns Trust, FACT Petitions FDA to Ban Poultry Litter as Cattle Feed (August 2009), http://www.foodanimalconcerns.org/PDF/filthyfeed_release_FINAL.pdf.

production, including a lack of uniform procedure to identify firms subject to the feed ban and inadequate oversight of cleaning procedures for feed transportation vehicles¹¹.

Animal feed imported to the United States should be monitored as well. Crump, et al, noted “there is considerable potential for contaminated animal feed or animal feed ingredients to move between and within countries. This could result in the widespread and rapid dissemination of a pathogen to geographically dispersed animal herds – and, in turn, to a range of human food products¹².” In 2007, melamine was discovered in gluten sources imported into the United States from China that was subsequently used in animal and pet food. Over 60 million packages of pet food were recalled and over 14,000 reports of pets were believed to have been sickened by the contaminated feed. The contaminated feed was also sent to hog farms in eight states resulting in over 6,000 hogs ordered to be quarantined or slaughtered¹³. Animal feed contaminated with BSE, melamine, *Salmonella*, and other contaminants pose serious health risks for both animals and humans, and the FDA should assure adequate oversight of the safe production of animal feed to prevent the spread of disease. For *Salmonella*, this should include maintaining the current CPG on *Salmonella* adulteration and rejecting the draft CPG which will weaken the existing safety standard.

CFA appreciates the opportunity to provide comments on this important topic.

Sincerely,



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¹¹ United States Government Accountability Office, *Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness* (2005) 1-30.

¹² Crump, John A., et. al., *Bacterial Contamination of Animal Feed and Its Relationship to Human Foodborne Illness*, *Food Safety* (2002) 859-865.

¹³ Barboza, David and Alexei Barrionuevo, *Filler in Animal Feed is Open Secret in China*, *New York Times* (April 30, 2007), <http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html>.