United States General Accounting Office

GAO

Report to the Honorable
Richard J. Durbin, United States Senate

September 2000

FOOD SAFETY

Controls Can Be Strengthened to Reduce the Risk of Disease Linked to Unsafe Animal Feed

GAO/RCED-00-255

Contents

Abbreviations

BSE	bovine spongiform encephalopathy
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
HACCP	hazard analysis and critical control point

GAO
Accountability * Integrity * Reliability

United States General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-285212

September 22, 2000

The Honorable Richard J. Durbin
United States Senate

Dear Senator Durbin:

The Centers for Disease Control and Prevention (CDC) estimates that each year in the United States over 5,000 people die and 76 million people become ill from unsafe food. One source of transmission of unsafe food is animal feed, which can contain harmful bacteria, such as *Salmonella*. While livestock or poultry may be immune to certain bacteria, human beings may not be. As a result, the food product containing these bacteria can cause illness, and even death, in the individual consuming it. Unsafe animal feed has also contributed to diseases such as bovine spongiform encephalopathy (BSE) in cattle, also known as "mad cow disease." In 1989, the United States banned the importation of cattle and animal feed from BSE-affected countries. BSE is thought to be linked to a fatal new human illness, known as new variant Creutzfeldt-Jakob Disease; in March 1996, the United Kingdom announced the first cases of this disease and linked it to BSE. By May 2000, 61 people in the United Kingdom, Ireland, and France had died from it, and the number and rate of new cases is increasing. Animal feed can also be contaminated with unsafe chemicals. For example, in 1999, animal feed contaminated with dioxin, a carcinogen, caused an estimated $850 million in losses to the Belgium livestock and poultry industries and resulted in elevated levels of the contaminant in persons who consumed the affected food products. Although these incidents have been limited to European countries to date, they demonstrate the devastating public health and economic consequences that can result from introducing contaminants into the feed supply.

Under the Federal Food, Drug, and Cosmetic Act, as amended, the Food and Drug Administration (FDA) is responsible for ensuring that animal feeds are safe and produce no human health hazards when used in food-producing animals. Under the Sanitary Food Transportation Act of 1990, the Department of Transportation was directed to issue new regulations to ensure that motor and rail vehicles used to transport food and food additives (including animal feed) do not also transport nonfood products that would make the food products unsafe to humans or animals. For example, in 1998, a feed ingredient became contaminated by metal

shavings while in transport, and animals in two states became ill when they ate the feed.

Concerned about the risks to human health posed by unsafe feed consumed by food-producing animals, you asked us to examine (1) the extent to which unsafe feed has been linked to human health problems in the United States and (2) the actions FDA and the Department of Transportation are taking to ensure the safety of animal feed.

To conduct this work, we reviewed scientific studies, reports, and other literature and spoke with experts in government, academia and private industry.[1]

Results in Brief

In the United States, only a relatively few incidents of human illness have been traced to contaminated animal feed. In terms of bacteria causing foodborne illnesses, although *Salmonella* is a known contaminant of animal feed, a direct link between the presence of bacteria in animal feed and human foodborne illness is difficult to document. Even when public health officials are able to trace the source of a disease to a food product, such as eggs, they cannot usually determine if the original source of the contamination is the animal feed, the improper handling of the product, or another factor. They are generally only able to determine how the food product became contaminated in certain situations, for example, when the bacteria identified is of an unusual strain or is from an unusual source. FDA has identified only two such incidents in the past 30 years. For example, in 1970, an outbreak of *Salmonella* that caused illness in several people was traced to a shipment of imported fish meal that chicken had consumed. FDA traced the source of this contamination because it involved a relatively rare strain of *Salmonella*. While livestock or poultry may in some cases be immune to the contaminants themselves, the food product from these animals can cause human illness. With respect to BSE in the United States, health officials have not identified any illness in livestock or in humans caused by this disease. However, the U.S. Department of Agriculture (USDA) has several studies underway to test sheep from three Vermont farms suspected of having BSE. These sheep had been imported from Belgium and the Netherlands in 1996. Finally, no reported incidents of

[1]Our review did not examine the use of antibiotics in animal feed and its potential effect on human health. We reported on this issue in April 1999: *Food Safety: The Agricultural Use of Antibiotics and Its Implications for Human Health* (GAO/RCED–99-74, Apr. 28, 1999).

human illness from chemically contaminated animal feed have been identified in the United States. However, illnesses from this source can take years to develop and would be difficult to link to animal feed.

FDA has taken some actions to better ensure the safety of animal feed, but problems such as lack of awareness of FDA's regulation, delays in issuing a new FDA regulation to strengthen controls over the bacterial contamination of feed, and the Department of Transportation's failure to issue regulations for the safe transport of animal feed, could lead to human illnesses. In 1997, FDA issued a regulation to prevent BSE in the United States. To assess compliance with this regulation, FDA and state inspectors have visited over 9,100 firms, such as farms that produce their own feed and rendering plants that process meat scraps for animal feed. Inspectors found that, among other things, nearly 1,700 firms were not aware of the regulation and thus could produce or use animal feed that was not in compliance. FDA officials also told us that the agency is developing a regulation to further strengthen controls over bacterial and other contaminants by, among other things, directing feed manufacturers to determine which hazards pose the greatest risks to the safety of their products and to establish controls to minimize these risks. However, FDA has not set time frames for completing this regulation. In addition, the Department of Transportation has not issued regulations to ensure the safe transportation of animal feed, as directed by the Sanitary Food Transportation Act of 1990. According to Transportation officials we spoke with, the Department has pursued a number of regulatory, administrative, and legislative initiatives to address the statutory mandate. The regulatory initiative, however, was not completed, primarily because the Department lacks resources for, and expertise in, food safety. Although animal feed contaminated during transport has caused animal deaths and illnesses, it has not resulted in any human deaths or acute illnesses. The public health and economic consequences that could result from the introduction of contaminants into the feed supply could be devastating.

This report is recommending that FDA develop and implement a BSE enforcement strategy to address the deficiencies identified in its inspections of animal feed firms and establish a schedule for completing a risk-based approach to ensuring the safety of animal feed. This report is also recommending that the President's Council on Food Safety work with the Department of Transportation and FDA, among others, to develop a regulatory strategy for ensuring the safe transportation of animal feed.

Background

Several federal agencies are responsible for ensuring the safety of animal feed and the U.S. food supply. Under the Federal Food, Drug, and Cosmetic Act, as amended, FDA has the authority to ensure that drugs and feeds given to animals are safe and properly labeled, and produce no human health hazards when used in food-producing animals. The act also gives FDA the authority to enforce the legal limits (tolerances) set by the Environmental Protection Agency on the amounts of pesticide residues that can be found in or on animal feed. In addition, the Department of Transportation (DOT) has the authority under the Sanitary Food Transportation Act of 1990 to prescribe regulations to safely transport food and animal feed. Finally, USDA's Animal and Plant Health Inspection Service is responsible for ensuring the health and care of animals and for improving agricultural productivity while contributing to the nation's economy and public health.

In addition to the agencies that have regulatory responsibilities, CDC is charged with using the best scientific information to monitor, investigate, control, and prevent public health problems. CDC provides scientific assessments of health threats and works closely with state and local health departments to monitor the frequency of specific diseases and conduct national surveillance. State and local agencies report known or suspected foodborne outbreaks to CDC. CDC then uses this information to identify patterns of related illnesses and works with state, local, and FDA officials to identify the source. Once the source is identified, state and local public health officials generally issue warnings to the public.

To carry out its feed safety responsibilities, FDA relies primarily on inspections of firms that manufacture animal feed products. These firms include the following:

- **Feed mills**, which are plants that combine various ingredients to produce an appropriate mix for a particular age or species of animal. Some feed mills are licensed by FDA to manufacture feed that contains certain medications, such as antibiotics.
- **Ruminant feeders**,[2] which are operations that feed and care for ruminant animals.

[2]A ruminant is an animal with a four-chambered stomach, like cattle, sheep, goats, buffalo, elk, and deer.

- **Rendering plants**, which are firms that process animals unfit for human consumption, meat scraps, or other slaughter by-products into animal feed ingredients and other products.
- **Protein blenders**, which are firms that obtain processed animal and vegetable protein from more than one source or from more than one species and subsequently mix, blend, or redistribute as animal feed or other products.

These firms are inspected by either FDA inspectors or state agencies that have entered into a contract to conduct these inspections in accordance with FDA's procedures and to be reimbursed by FDA. Under state partnership agreements, states agree to conduct inspections under their own authorities without federal funding and to share the results with FDA. Inspections of these firms play a major role in ensuring the safety of the nation's feed supply. State governments play a central role in conducting these inspections.

During fiscal years 1998 and 1999, FDA's animal feed inspections were conducted under two programs: Feed Contaminants and Medicated Feeds. Under the Feed Contaminants program, inspectors investigate reports of violative feed samples and conduct random inspections and surveillance to ensure that the health of animals is not impaired and that human health is not compromised by food products derived from food-producing animals fed contaminated animal feed. The firms inspected are selected according to a number of criteria, such as how long it has been since their last inspection and how many problems have been noted with the firm in recent years. Inspectors also sample and analyze animal feed for contamination by pesticides, industrial chemicals, metal, and bacterial agents.[3] Most of these inspections are performed by state inspectors, and FDA does not maintain a database on the number of inspections completed or their results. During fiscal years 1998 and 1999, FDA devoted a total of about 27 staff years to this program.

FDA and state inspectors conduct Medicated Feeds inspections of firms licensed to include certain medications in the animal feed they

[3]To enforce the legal limits set by the Environmental Protection Agency on the amount of pesticide residues that can be found in or on animal feed, FDA samples both domestically produced and imported feeds and analyzes them for pesticide residues. If illegal residue levels are found, FDA can invoke various sanctions, such as seizure or injunction. FDA's monitoring focuses on feeds for livestock and poultry because these animals ultimately become, or produce, food for human consumption.

manufacture. Inspectors determine whether the firms are in compliance with good manufacturing practice regulations under the Federal Food, Drug, and Cosmetic Act, encourage voluntary corrective action by the establishment when appropriate, and initiate administrative and/or regulatory action against violative firms and their products. In accordance with statutory requirements, FDA is required to inspect registered firms every 2 years. During fiscal years 1998 and 1999, FDA devoted a total of about 34 staff years to this program and, together with state officials, completed a total of 1,299 inspections: 496 by FDA, 729 by state contracts, and 74 by partnership agreements.

To prevent the emergence of BSE through unsafe feed in the United States, FDA issued a new regulation in June 1997 that prohibits the feeding of certain proteins derived from mammals to ruminant animals, such as cattle. Shortly thereafter, as a part of its Feed Contaminants and Medicated Feeds inspection programs, FDA initiated additional inspections of feed manufacturers. From January 1998 through January 2000, FDA and state inspectors inspected over 9,100 firms to increase industry awareness of this regulation. FDA told us the primary purpose of these inspections was to educate the industry about the new required procedures. According to FDA, it took only limited enforcement actions against firms that were not in full compliance with the new regulation.

Almost No Human Illnesses Have Been Traced to Animal Feed in the United States

In the United States, few incidents of human illness have been traced to contaminated animal feed. With respect to bacterial contamination, even though *Salmonella* is a known contaminant of animal feed, FDA has identified only two incidents of human illness resulting from contaminated feed in the past 30 years. Such incidences may be higher, but investigators are not generally able to trace the source of contamination beyond the immediate food product that caused the illness. With respect to BSE, U.S. health officials have not identified any illnesses in livestock or humans from this disease, although USDA studies are currently underway to test sheep on three Vermont farms to determine if they have BSE. These sheep were imported from Belgium and the Netherlands in 1996. FDA has not identified any incidents of human illness resulting from chemically contaminated animal feed in the United States. However, any such illness could take years to develop and would be difficult to link to animal feed.

Direct Link Between Animal Feed Contaminated With Bacteria and Human Illness Is Difficult to Document

Public health officials have identified only two incidences of human illness resulting from bacteria-contaminated animal feed in the past 30 years. In 1970, an outbreak of a relatively rare strain of *Salmonella* in chicken caused illness in several people. Because of the rarity of the strain, FDA decided to track the source of the contamination, eventually tracing it to imported fish meal fed to chickens. FDA is still investigating a second incident from 1999 involving 11 Canadian children who became ill from handling pet treats contaminated with *Salmonella*. FDA has established that these treats were also sold in the United States. Animals that consume contaminated animal feed may not become ill, but food products from these animals can cause human illness.

More incidences of foodborne illness resulting from bacteria-contaminated animal feed may have occurred; however, public health officials typically only attempt to trace the source to the food product consumed by those who became ill. When the contaminated food product is identified, public health officials generally only try to determine the original source of the contamination in certain situations, for example, when the bacteria identified is of an unusual strain or is from an unusual source, such as the pet treats. Such an investigation is rare primarily because of the difficulty in identifying the original cause of the contamination. A food product that contains *Salmonella*, for example, could have acquired the pathogen simply because someone handling the product did not properly wash his or her hands. Nonetheless, 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 high.

No Incidences of BSE Have Been Identified in the United States

As of January 2000, USDA's Animal and Plant Health Inspection Service had collected brain matter from nearly 10,000 cattle from nearly every state. The samples were from cows with central nervous system disorders displaying BSE-like symptoms. However, none of these samples tested positive for BSE. USDA officials told us, however, that sheep on three farms in Vermont have recently tested positive for a BSE-like disease. These sheep had been imported from Belgium and the Netherlands in 1996. The USDA studies are currently underway to determine if the disease is BSE or a related disease. Health officials have not reported any incidents of new variant Creutzfeldt-Jakob Disease in the United States.

BSE is one of the most significant threats to human health that can result from unsafe animal feed. Researchers have been unable to fully agree on

either the agent that causes BSE or its source. Most believe that the disease is caused by abnormal proteins found in the brains of cattle and that the cattle contract the disease from feed containing animal by-products.

Any case of BSE reported in the United States would increase concerns about a related risk to public health and have a potentially major economic impact on the domestic feed, dairy, and beef industries. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service estimates that as of 1999, the cost of BSE in the United Kingdom had reached $6.74 billion. As of December 31, 1999, BSE had caused over 176,000 cattle to be destroyed in the United Kingdom, and the disease has spread to France, Portugal, and other European nations. Moreover, as of May 2000, health officials have verified a total of 61 human deaths caused by new variant Creutzfeldt-Jakob Disease in the United Kingdom, Ireland, and France.[4]

Direct Link Between Chemically Contaminated Animal Feed and Human Illness Is Difficult to Document

As of July 2000, there have been no reported cases in the United States of human illness resulting from chemically contaminated animal feed. However, any such illness could take years to develop and would be difficult to link to animal feed. During fiscal years 1998 and 1999, less than 3 percent of animal feed samples tested for pesticides contained residue levels above established tolerances, according to the results of FDA's testing for its residue monitoring program. Animal feed can also be contaminated with dioxin, which occurs naturally in the environment or can be a by-product of a manufacturing process. In 1997, dioxin was discovered in animal feed used for poultry, fish, hogs, and cattle. This discovery prompted FDA to stop the use of the feed, to require producers to test dioxin levels in the animals that had consumed the feed, and finally, to restrict the sale of some food products.[5]

Chemically contaminated feed could result in serious economic harm. For example, in 1999, animal feed contaminated with dioxin caused an estimated $850 million in losses to the Belgium livestock industry, loss of export markets for Belgian products, a significant loss of confidence by

[4]In 1989, the Animal and Plant Health Inspection Service began prohibiting imports of cattle and beef products, as well as animal feed, from BSE-affected countries.

[5]*Food Safety: Agencies' Handling of a Dioxin Incident Caused Hardships for Some Producers and Processors* (GAO/RCED-98-104, Apr. 10, 1998).

European consumers in the safety of their food supply, and contributed to the resignation of Belgium's Ministers of Health and Agriculture.

Efforts Are Being Made to Better Ensure the Safety of Animal Feed, but Further Improvements Are Possible

The public health and economic consequences to the nation's feed, dairy, meat and poultry industries that can result from contaminants in the feed supply can be devastating. Because of this, FDA is taking action to better ensure the safety of animal feed. However, compliance issues with its BSE regulation and delays in issuing a new feed ingredient regulation that will strengthen controls over bacterial contamination could result in human illness. Furthermore, according to Department of Transportation officials we spoke with, the Department has not issued any regulation or guidance on the safe transportation of animal feed, in part because it lacks resources and food safety expertise.

BSE Regulation Has Not Been Fully Implemented by the Feed Industry

To determine how firms were implementing the June 1997 BSE regulation, FDA, with the assistance of state officials, inspected over 9,100 firms from January 1998 through January 2000. Table 1 shows the types and number of firms inspected.

Table 1: Types of Firms Inspected

Type of firm	Number of firms inspected
Licensed feed mill	1,029
Nonlicensed feed mill	4,901
Ruminant feeder	1,400
Dairy farm	495
Renderer	211
Protein blender	121
Other[a]	1,027
Total	**9,184**

[a] Includes haulers and distributors of feed, and firms or persons who receive prohibited materials directly from manufacturers.

Source: FDA.

The BSE inspection results revealed that 1,688 of the 9,184 firms were not aware of the new BSE feed regulation. Furthermore, inspection results of the 2,481 firms that were identified as handling "prohibited" material—

material that is not allowed to be fed to ruminants—revealed some serious deficiencies. For example:

- **Required cautionary statement not on product label**. Of the firms inspected, 699, or 28 percent, did not label their products with the required cautionary statement that the feed should not be fed to cattle or other ruminants.
- **Required records not properly maintained**. One-hundred and thirty-seven firms, or about 6 percent, did not properly maintain the name and address of the consignee of their products, which would make it difficult to trace sales of contaminated feed.

In addition, of the 1,771 firms that manufacture both prohibited and nonprohibited material, 361, or 20 percent, did not have a system in place to prevent commingling and cross-contamination, as required by the regulation.

Because renderers and FDA-licensed feed mills are at the greatest risk of introducing BSE to a wide segment of the animal feed market, the inspection results for these firms were particularly disturbing. For example,

- Twenty-three of the 211 renderers inspected, about 11 percent, were not aware of the BSE regulation.
- Twenty-seven of the 163 renderers that handle prohibited material, about 17 percent, did not label their products with the required cautionary statement.
- Ten of the 63 renderers that manufacture both prohibited and nonprohibited material, about 16 percent, did not have a system in place to prevent commingling.

The results for the FDA-licensed feed mills were similar. For example,

- Sixty-three of the 1,023 mills, about 6 percent, were not aware of the regulation.
- Eighty-five of the 409 mills that handle prohibited material, about 21 percent, did not label their products with the required cautionary statement.
- Thirty-seven of the 300 mills that manufacture both prohibited and nonprohibited material, about 12 percent, did not have a system in place to prevent commingling.

FDA told us that as a result of the BSE inspections, two warning letters have been issued and five firms have voluntarily recalled products. As of July 2000, however, FDA had not completed its analysis of the inspection results and had not updated its enforcement strategy for achieving industry compliance with the BSE regulation. FDA also told us that the next rounds of BSE inspections will include only those firms that handle prohibited material. In addition, FDA told us it will direct its efforts towards those firms or segments of the industry that are not in compliance with the regulation.

FDA Has Not Established a Time Frame for Issuing a New Regulation to Strengthen Controls for Microbial Contamination

FDA is drafting a new regulation to strengthen controls over bacterial and other contaminants in animal feed but has not established a timetable for its issuance. FDA told us the new regulation is intended to limit contamination in feed ingredients and will require manufacturers to (1) evaluate all hazards associated with their feed ingredients, including but not limited to microbial hazards; (2) determine which hazards pose a risk to the safety of the product; and (3) establish controls to minimize these risks. FDA also told us the new regulation would be modeled after the hazard analysis and critical control point (HACCP) management practices currently followed by nearly all firms that handle meat, poultry, and seafood.[6]

Recent studies of animal feed demonstrate the need for this new regulation. For example, several recent studies by USDA and others show evidence of *Salmonella* in animal feed and in rendered animal proteins that often become ingredients in animal feed.

No Regulations Issued to Safeguard the Transport of Animal Feed

As of July 2000, the Department of Transportation had not issued regulations to ensure the safety of food, including animal feed, during transport by rail vehicles or trucks, as directed by the Sanitary Food Transportation Act of 1990. Transportation officials pursued a number of

[6]The HACCP program is designed to identify the steps in food production where contamination is most likely to occur and then establish controls that prevent or reduce contamination. HACCP management involves seven principles based on scientific and technical knowledge: (1) conduct a hazard analysis, (2) identify critical control points, (3) establish critical limits for each critical control point, (4) establish monitoring requirements, (5) establish corrective actions, (6) establish record-keeping procedures, and (7) establish verification procedures. See, for example, *Meat and Poultry: Improved Oversight and Training Will Strengthen New Food Safety System* (GAO/RCED-00-16, Dec. 8, 1999).

regulatory, administrative, and legislative initiatives to address the statutory mandate but cited lack of resources and expertise in food safety as the primary reasons for not issuing the regulations. They informed us that for fiscal year 2000, the Department requested $150,000 to fund three new staff positions—two of which were for sanitary food liaisons. The sanitary food liaisons would have been responsible for developing regulations to ensure the safety of food and feed during transport. They further advised us that funding for these positions was denied. They did not request funding for the positions for fiscal year 2001. Although FDA told us its staff has the required expertise, it believes these responsibilities should remain with the Department of Transportation. FDA said the responsibilities set forth in the Sanitary Food Transportation Act are an extension of Transportation's responsibility to protect the public.

FDA told us it has documented several instances in which animal feed was contaminated while in transport. For example, in 1998, a feed ingredient became contaminated by metal shavings while in transport, and animals in two states became ill when they ate the feed containing the contaminated feed ingredient. In two earlier incidents documented by FDA, livestock became ill or died as a result of being fed grain contaminated by a chemical that had previously been transported in the same rail vehicle. FDA officials told us that these incidents resulted in the illness or death of many animals. Fortunately, the contamination did not cause any human deaths or acute illnesses.

The President's Council on Food Safety may be a vehicle for helping to resolve implementation issues associated with regulating animal feed during transport. The Council, formed on August 25, 1998, by executive order of the President, was established to improve the safety of the nation's food supply through science-based regulation and well-coordinated inspection, enforcement, research and education. The Council is expected to, among other things, recommend to the President how to advance federal efforts to implement a comprehensive science-based strategy to improve the safety of the food supply and enhance coordination among federal agencies, state, local and tribal governments, and the private sector.

Conclusions

Few incidents of human illness in the United States have been linked directly to contaminated animal feed because public health investigations of foodborne illness cannot usually determine if the original source of the contamination is the feed, handling of the product, or another factor. However, the serious deficiencies disclosed by recent feed manufacturer

inspections and the potentially major public health and economic consequences that could result from the introduction of contaminants into the feed supply, suggest a need for strong regulatory controls. These consequences became quite clear in the United Kingdom, France, and Ireland, where 61 persons have died since 1996 from illnesses linked to BSE; the economic losses resulting from BSE have been estimated to exceed $6 billion in the United Kingdom. While FDA is taking action to strengthen control systems, unfamiliarity with FDA's new BSE regulation and delays in issuing a new regulation to strengthen controls over bacterial contamination of animal feed need to be addressed. Furthermore, there is a need to ensure that animal feed is not contaminated during transport. The President's Council on Food Safety may be a vehicle that could be of assistance in helping the Department of Transportation and the FDA to resolve implementation issues associated with regulating animal feed during transport.

Recommendations for Executive Action

To ensure that animal feed in the United States remains free of contaminants that would cause BSE, we recommend that the Commissioner of FDA develop and implement an enforcement strategy that contains specific goals and time frames for establishing a system to correct the deficiencies identified during the agency's 2 years of inspecting animal feed firms and to ensure that firms in the future continue to remain in compliance with the regulation.

We further recommend that the Commissioner establish a schedule for completing the agency's HACCP-based approach for ensuring the safety of animal feeds.

To ensure the safe transportation of animal feed, we recommend that the President's Council on Food Safety work with the Department of Transportation and FDA, among others, to develop a strategy to regulate animal feed while in transport.

Agency Comments

We provided a draft copy of this report to FDA, CDC, the Department of Transportation, and the President's Council on Food Safety for their review and comment. FDA agreed with all three of our recommendations and stated that it (1) has initiated an enforcement strategy that will correct the deficiencies identified during the initial round of BSE inspections to help ensure a high rate of compliance in the future; (2) has placed issuing the

new feed regulation on its priority list; and (3) agreed to cooperate with and assist the President's Council on Food Safety and the Department of Transportation to develop a strategy for regulating animal feed while it is in transit. With regard to FDA's response to the first recommendation, while we agree that FDA has initiated an enforcement strategy, we believe that the strategy, which was developed in December 1998, needs to be updated to include specific goals and time frames to correct existing deficiencies and to ensure that firms continue to remain in compliance with the regulation.

CDC said it believed the draft report inappropriately implied that contaminated animal feed is an infrequent cause of human illness. CDC said that contaminated animal feed could actually be an important source of *Salmonella* and other causes of human illness, but important gaps in national surveillance data make it nearly impossible to follow the chain of events from farm to table to implicate contaminated animal feed as the source of human illness. We have revised to our report to further highlight that microbial agents in animal feed pose a risk to human health.

We met with officials from the Department of Transportation, including the Associate Administrator for Hazardous Materials Safety, and they provided oral comments on our draft report. Department officials stated that the report provided an accurate overview of the issues, and they agreed with our recommendation that the Department work with the President's Council on Food Safety and FDA to develop a strategy to regulate animal feed while in transport. In addition, the Department provided several technical and clarifying comments that we incorporated into the report as appropriate.

The President's Council on Food Safety concurred with the recommendation that it should work with FDA and the Department of Transportation, among others, to develop a strategy to regulate animal feed while in transport.

FDA and CDC provided a number of editorial and technical comments, which we incorporated into the report as appropriate. Comments from FDA, CDC, and the President's Council on Food Safety and our responses are included as appendixes I through III.

Scope and Methodology

To determine the extent to which unsafe feed has been linked to human health problems in the United States, we interviewed officials and reviewed records from the FDA, the National Institutes of Health, CDC, and USDA's Animal and Plant Health Inspection Service. We also discussed this issue with USDA's Food Safety and Inspection Service and the Environmental Protection Agency. In addition, we interviewed industry trade officials from the American Feed Industry Association, the National Grain and Feed Association, the National Cattlemen's Beef Association, the National Milk Producers Federation, and the National Renderers Association. In addition, we spoke with researchers from the Harvard Center for Risk Analysis.

To determine the actions FDA and the Department of Transportation are taking to ensure the safety of animal feed, we reviewed inspection reports from FDA's Feed Contaminants and Medicated Feeds inspection programs and interviewed officials with the Department of Transportation and with FDA about provisions for the safe transport of feed contained in the Sanitary Food Transportation Act of 1990. We also discussed this issue with the President's Council on Food Safety. In addition, we analyzed FDA's BSE inspection results and reviewed its enforcement strategy for achieving industry compliance with the BSE regulation. Finally, we interviewed FDA officials about their efforts to address the potential for bacterial contamination in animal feed. We also visited a feed mill to observe procedures for manufacturing feed and analyzing feed ingredients.

We performed our review from November 1999 through August 2000 in accordance with generally accepted government auditing standards.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies of this report to the congressional committees with jurisdiction over food safety issues; the Honorable Dan Glickman, Secretary of Agriculture, and the Honorable Donna E. Shalala, Secretary of Health and Human Services, in their capacities as co-chairs of the President's Council on Food Safety; the Honorable Rodney E. Slater, Secretary of Transportation; the Honorable Jane Henney, M.D., Commissioner of the Food and Drug Administration; the Honorable Neal Lane, Co-Chair, President's Council on Food Safety; the Honorable Jeffrey P. Koplan, Director, Centers for Disease Control and Prevention; and the Honorable Jacob J. Lew, Director, Office of

Management and Budget; and other interested parties. We will also make copies available upon request.

If you or your staff have any questions about this report, please contact me at (202)-512-5138. Key contributors to this report were Robert C. Summers, John M. Nicholson Jr., Stuart Ryba, and Janice M. Turner.

Sincerely yours,

Lawrence J. Dyckman,
Director, Food and
Agriculture Issues

Comments From the Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Mr. Lawrence J. Dyckman
Director, RCED Division
Food and Agriculture Issues
U.S. General Accounting Office
441 G Street, N.W., Room 2T23
Washington, D.C. 20548

Dear Mr. Dyckman:

Enclosed are the Food and Drug Administration's comments on the GAO draft report entitled, FOOD SAFETY: Controls Can Be Strengthened to Reduce Risk of Disease Linked to Unsafe Animal Feed, GAO/RCED-00-255.

If we can be of further assistance, please call Lois Adams at (301) 827-0125.

Sincerely,

Melinda K. Plaisier
Associate Commissioner
for Legislation

Enclosure

FOOD AND DRUG ADMINISTRATION COMMENTS ON THE GENERAL ACCOUNTING OFFICE DRAFT REPORT ENTITLED, FOOD SAFETY; Controls Can BE Strengthened to Reduce Risk of Disease Linked to Unsafe Animal Feed (GAO/RCED-00-255)

GENERAL COMMENTS

The Food and Drug Administration appreciates the opportunity to review and offer comments on this draft report. In general, we agree with the draft report.

GAO RECOMMENDATON

To ensure that animal feed in the United States remains free of contaminants that would cause BSE, we recommend that the Commissioner of FDA develop and implement an enforcement strategy that contains specific goals and time frames for establishing a system to correct the deficiencies identified during its 2 years of inspecting animal feed firms and to ensure that firms in the future continue to remain in compliance with the regulation.

FDA COMMENT

FDA concurs. FDA has an enforcement strategy that we believe will correct the deficiencies identified during the initial round of inspections and help to ensure a high rate of compliance in the future.

GAO RECOMMENDATION

We further recommend that the Commissioner establish a schedule for completing its HACCP-based approach for ensuring the safety of animal feeds.

FDA COMMENT

FDA concurs.. In fact, issuance of this regulation is already on our priority list to be developed and issued over the next few years. This list is reviewed monthly and updated as needed. FDA will initiate development of a HACCP-based regulation for ensuring the safety of animal feeds as other, higher-priority efforts are completed. As the draft report notes, however, there have been no identified illnesses in livestock or humans caused by BSE or chemically contaminated animal feed in the United States. We believe the already issued regulations regarding the production of safe animal feed and banning the importation of cattle and animal feed from BSE-affected countries have significantly contributed to prevention of such illnesses in this country.

GAO RECOMMENDATION

To ensure the safe transportation of animal feed, we recommend that the President's Council on Food Safety work with the Department of Transportation and the Food and Drug Administration, among others, to develop a strategy to regulate animal feed while in transport.

FDA COMMENT

FDA agrees to cooperate with and assist the President's Council on Food Safety and the Department of Transportation to develop a strategy for regulating animal feed while it is in transit.

Comments From the Centers for Disease Control and Prevention

Note: GAO's comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 22 2000

Lawrence J. Dyckman, Director
Food and Agriculture Issues
Resources, Community, and Economic Development Division
U.S. General Accounting Office
Washington, D.C. 20548

Dear Mr. Dyckman:

Thank you for the opportunity to review the GAO draft report, "Food Safety: Controls Can Be Strengthened to Reduce Risk of Disease Linked to Unsafe Animal Feed" (GAO/RCED-00-255). The Centers for Disease Control and Prevention (CDC) is very concerned about the risks to human health posed by unsafe feed consumed by food-producing animals. As the draft report points out, instances of contaminated animal feeds in European countries demonstrate the devastating public health and economic consequences that can result from the introduction of these contaminants into the feed supply. However, CDC feels that the draft report contains serious omissions which can lead readers to inappropriate conclusions. Our greatest concerns relate to the following issues.

See comment 1.

1. Frequency at which human illness results from contaminated animal feed: The draft report provides a narrow explanation for the rarity of reported episodes of human illness attributed to contaminated feed, and therefore inappropriately implies that contaminated animal feed is an infrequent cause of human illness. Contaminated animal feed could actually be an important source of *Salmonella* and other causes of human illness, but important data gaps make it nearly impossible to follow the chain of events from farm-to-table to implicate contaminated animal feed as the source of human illness.

Food animals are the reservoir for several foodborne bacteria (*i.e.*, *Salmonella*, *Campylobacter*, *E. coli* O157:H7, *Yersinia*). Food animals typically acquire these bacteria while on the farm, and this can occur through contaminated feed, especially in the case of *Salmonella*. Therefore, the source for contamination of foods of animal origin with these bacteria, and thus the source of human illness, often occurs "on the farm." The ultimate sources of the strains that cause the illness, including contaminated feeds, are rarely determined–as noted in the draft report, on-farm investigations are in general rare, and they are difficult to carry out. However, we should not confuse the lack of information with the absence of a problem. The well-documented episode of *Salmonella* Agona contamination of chicken feed that happened in the 1970s is mentioned in the draft report. In that episode, *Salmonella* Agona was introduced around the world to many countries simultaneously via a contaminated feedstuff. It is illustrative of the potential for global distribution of a pathogen via contaminated feed, which could be happening often with more common serotypes.

Page 2 - Lawrence J. Dyckman

2. Frequency at which animal feeds are contaminated with Salmonella: The draft report does not mention that *Salmonella* is frequently isolated from animal feed, particularly feeds containing animal protein. Such findings have been reported numerous times in the medical and veterinary literature. A standing committee of the U.S. Animal Health Association publishes an annual summary of the issue (The most recent report is at website: http://www.usaha.org/reports/reports99/r99feed.html). The Animal Protein Producers Industry conducts sampling and has recently conducted a substantial survey of the quantitative levels of contamination of feed, finding that in the summer months it rises as high as an average of 78 *Salmonella* organisms per gram. In a review of the problem published in 1981, Williams reported that poultry feed has been well documented as a source of *Salmonella* contamination for poultry flocks and subsequently processed carcasses (*Salmonellas in poultry feed–a worldwide review*. Worlds Poultry Assn J 37:6-19, 1981). Recently researchers at Washington State University have isolated *Salmonella* Typhimurium DT104 from animal feed. These findings indicate that contaminated animal feed could be an important source for the introduction of *Salmonella* into animal herds and flocks in general, and specifically of *S.* Typhimurium DT104 in the United States, thereby contributing to its dissemination among food animals and ultimately resulting in human illness. *Salmonella* Typhimurium DT104 currently causes about 8% of the approximately 1.4 million human *Salmonella* infections which occur each year in the United States. The frequent isolation of *Salmonella* from animal feed indicates that contaminated animal feed is a potentially important source of dissemination of *Salmonella*, and ultimate source of human *Salmonella* infections.

See comment 2.

Additionally, the draft report does not mention that the measurement of contamination is critically dependent on the microbiological methods used. With sensitive methods, the rates of contamination of some animal feeds may be extremely high.

3. Lack of surveillance data represents gaps in national surveillance: The draft report does not mention that the lack of routine national monitoring of the contamination of animal feed represents a significant gap in our national surveillance and limits intervention efforts for the prevention of human illness. Animal feed sampling is an integral part of the national food borne disease surveillance in several European countries. Over time, surveillance for animal feed contamination in these countries has contributed to a low prevalence of contamination and fewer human infections. For example, sampling of animal feed for *Salmonella* is a central feature of the Danish *Salmonella* control program (Annual reports on zoonoses in Denmark 1998 at http: //www.svs.dk).

See comment 3.

In the United States, the only monitoring of animal feed for *Salmonella* is limited sampling conducted not by a government agency, but by the rendering industry. Results of this sampling, which should be included in this draft report, are reported annually in the Proceedings of the United States Animal Health Association, and typically does not include serotype.

In addition to these concerns, specific technical comments and suggestions are provided below for your consideration.

Technical Comments to GAO Draft Report

Now on p. 10.

See comment 4.

1. Pages 1 and page 10: We suggest that the report, when describing the impact of nvCJD, not just report the fact that by May 2000, 61 people had died, but in addition also include the fact that "the number and rate of new cases is increasing."

See comment 5.

2. Pages 2, 8 and 9: Where the draft report mentions 1,700 firms of 9,100 firms not being aware of FDA's 1997 new feed regulation when surveyed in 1998 and 1999, it would be helpful to include an estimate from FDA about how this translates into the percentage of animal feed in the United States at risk. It is possible that the major producers of feed in the United States were more likely to be aware of the new regulation and to have responded appropriately to it.

Now on pp. 9 and 10.

See comment 4.

3. Page 6, para. 3: Suggest deleting the sentence, "Researchers have been unable to ascertain either the agent that causes BSE or its source." The next sentence could then be modified slightly to read as follows: "Most researchers believe BSE is caused by abnormal proteins that collect in the brains of cattle and that the cattle contract the disease from feed containing animal by-products contaminated with these abnormal proteins."

Now on p. 10.

See comment 4.

4. Page 6, last para., sentence 1: Suggest modifying the sentence to read, "Any case of BSE reported in the United States would increase concerns about a related risk to public health and could have a potentially major economic impact on the domestic feed, dairy, and beef industries."

See comment 5.

5. Pages 7-9: The data for 1998 and 1999 were combined; however, it is likely that the awareness and compliance with the FDA regulation would have been increasing over time. By combining these data, the unstated implication is that the data from the two years were not much different from each other. We suggest that the data be checked to make sure that there indeed was no marked change in the results of the survey over this two year period.

If you have any questions concerning these comments, please have your staff contact me, or Joe Davis at (404) 639-4002.

Sincerely,

James D. Seligman
Associate Director for
Program Services

GAO's Comments

1. We agree. Contaminated feed could be an important source of *Salmonella* and other causes of human illness. However, as we state in the report, a direct link between the presence of bacteria in feed and human illness is difficult to document.

2. We agree and have revised our report to recognize the findings of the U.S. Animal Health Association.

3. We agree and have revised our report to include data from the U.S. Animal Health Association.

4. We agree and have revised our report.

5. We agree. However, because FDA has not completed its analyses of the BSE inspection data, we were unable to compare the results of (1) major producers' awareness of the regulations versus small producers' awareness and (2) inspection deficiency rates in 1998 compared with 1999.

Comments From the President's Council on Food Safety

THE WHITE HOUSE
WASHINGTON

August 16, 2000

Mr. Lawrence J. Dyckman
Director
Food and Agriculture Issues
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Dyckman:

Thank you for the opportunity to provide you with comments on the draft report "Food Safety: Controls Can be Strengthened to Reduce Risk of Disease Linked to Unsafe Animal Feed (GAO/RCED-00-255)." As co-chair of the President's Council on Food Safety, I concur with your recommendation that the Council "work with the Department of Transportation and the Food and Drug Administration, among others, to develop a strategy to regulate animal feed while in transport." Over the next several weeks, my staff will initiate an interagency process, under the auspices of the Council, to act on this recommendation.

Sincerely,

Neal Lane

Neal Lane
Assistant to the President
for Science and Technology

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