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MAD COW DISEASE

FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness



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Highlights of [GAO-05-101](#), a report to congressional requesters

Why GAO Did This Study

More than 5 million cattle across Europe have been killed to stop the spread of bovine spongiform encephalopathy (BSE), commonly called mad cow disease. Found in 26 countries, including Canada and the United States, BSE is believed to spread through animal feed that contains protein from BSE-infected animals. Consuming meat from infected cattle has also been linked to the deaths of about 150 people worldwide. In 1997, the Food and Drug Administration (FDA) issued a feed-ban rule prohibiting certain animal protein (prohibited material) in feed for cattle and other ruminant animals. FDA and 38 states inspect firms in the feed industry to enforce this critical firewall against BSE. In 2002, GAO reported a number of weaknesses in FDA's enforcement of the feed ban and recommended corrective actions. This report looks at FDA's efforts since 2002 to ensure industry compliance with the feed ban and protect U.S. cattle.

What GAO Recommends

GAO recommends FDA, among other things, develop procedures for finding additional firms subject to the feed-ban and using tests to augment inspections. FDA said the study was thorough but disagreed on four of nine recommendations. GAO continues to believe that, given the discovery of BSE in North America and the oversight gaps described in the report, the recommended actions are needed to protect U.S. cattle from BSE.

www.gao.gov/cgi-bin/getrpt?GAO-05-101.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robert A. Robinson at (202) 512-3841 or robinsonr@gao.gov.

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What GAO Found

FDA has made needed improvements to its management and oversight of the feed-ban rule in response to GAO's 2002 report, but program weaknesses continue to limit the effectiveness of the ban and place U.S. cattle at risk of spreading BSE. Improvements made include FDA establishing a uniform method of conducting compliance inspections and training FDA inspectors, as well as state inspectors who carry out inspections under agreements with FDA, on the new method. FDA also implemented new data-entry procedures that are designed to more reliably track feed-ban inspection results. Consequently, FDA has a better management tool for overseeing compliance with the feed-ban rule and a data system that better conforms to standard database management practices. However, various program weaknesses continue to undermine the nation's firewall against BSE. For example:

- FDA acknowledges that there are more feed manufacturers and transporters, on-farm mixers, and other feed industry businesses that are subject to the feed ban than the approximately 14,800 firms inspected to date; however, it has no uniform approach for identifying additional firms.
- FDA has not reinspected approximately 2,800, or about 19 percent, of those businesses, in 5 or more years; several hundred are potentially high risk. FDA does not know whether those businesses now use prohibited material in their feed.
- FDA's feed-ban inspection guidance does not include instructions to routinely sample cattle feed to test for potentially prohibited material as part of the compliance inspection. Instead, it includes guidance for inspectors to visually examine facilities and equipment and review invoices and other documents.
- Feed intended for export is not required to carry a caution label "Do not feed to cattle or other ruminants," when the label would be required if the feed were sold domestically. Without that statement, feed containing prohibited material could be inadvertently or intentionally diverted back to U.S. cattle or given to foreign cattle.
- FDA has not always alerted USDA and states when it learned that cattle may have been given feed that contained prohibited material. This lapse has been occurring even though FDA's guidance calls for such communication.
- Although research suggests that cattle can get BSE from ingesting even a small amount of infected material, inspectors do not routinely inspect or review cleanout procedures for vehicles used to haul cattle feed.

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Abbreviations

APHIS	Animal and Plant Health Inspection
BSE	bovine spongiform encephalopathy
DNA	deoxyribonucleic acid
FACTS	Field Accomplishments and Compliance Tracking System
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
PCR	polymerase chain reaction
TSE	transmissible spongiform encephalopathy
USDA	United States Department of Agriculture
vCJD	variant Creutzfeldt-Jacob disease

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United States Government Accountability Office
Washington, D.C. 20548

February 25, 2005

The Honorable Saxby Chambliss
Chairman
The Honorable Tom Harkin
Ranking Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

The Honorable Thad Cochran
The Honorable Richard J. Durbin
United States Senate

Bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, is an always fatal neurodegenerative animal disease that has been found in cattle in 26 countries since it was first identified in the United Kingdom in 1986. In December 2003, the United States discovered its first case of BSE in a cow in Washington State. The U.S. Department of Agriculture (USDA) later determined that this cow was imported from Canada. The agent believed to be responsible for BSE is a malformed type of protein called a prion, found in certain tissue—particularly brain and central nervous system tissue—of infected animals. Cattle contract BSE by eating feed derived from the remains of BSE-infected animals.¹ In Europe, more than 5 million head of cattle have been killed to thwart the spread of the disease. Scientists also generally believe that a fatal disease in humans—known as variant Creutzfeldt-Jacob Disease (vCJD)—is linked to eating beef contaminated with the malformed protein. Research suggests that vCJD is difficult for humans to contract—about 150 people have died worldwide from vCJD. Both diseases have long incubation periods during which they are undetectable—2 to 8 years in cattle and possibly up to 30 years in humans.

USDA is primarily responsible for detecting the disease in cattle, and the Department of Health and Human Services' Food and Drug Administration (FDA) is primarily responsible for preventing its introduction and spread through animal feed. Both agencies recognize the importance of preventing BSE from becoming established in the United States—not only to protect the safety of the U.S. food supply but also to protect the economic viability

¹It is a common nutritional practice to add protein (derived from animals or plants) to speed animal growth.

of the \$70 billion U.S. beef industry. With 95 million head of cattle, the United States is the world's largest beef producer, exporting a record 2.6 billion pounds of beef, valued at over \$3.1 billion, in 2003. In January 2002, we reported that the potential impact of even a small outbreak of BSE in the United States could be economically devastating.² Indeed, between January and September 2004, the industry lost more than 80 percent of its export trade, or an estimated \$2 billion, following the discovery of the one BSE-infected animal in December 2003. Although most countries stopped importing U.S. beef for some period of time, domestic consumption did not drop. In fact, changing dietary trends have led to increased U.S. beef consumption in the last several years. The United States is in discussions with its major trading partners about renewing U.S. beef imports.

To protect U.S. cattle and consumers, USDA and FDA have put in place three primary firewalls. These include the following:

- *Controls over imports.* Since 1989, USDA has prohibited the importation of live cattle and certain cattle products from countries where BSE is known to exist. In 1992, FDA began identifying medical products and other FDA-regulated foods and products derived from cattle from countries with BSE. USDA and FDA, in cooperation with the Department of Homeland Security's Customs and Border Protection, screen shipments of such products.
- *Animal surveillance.* Since 1990, to detect BSE, USDA has been testing brain tissue, primarily from cattle that exhibit neurological symptoms and adult cattle that die from unknown causes, as well as from cattle slaughtered for meat.
- *Feed ban.*³ In 1997, FDA banned the use of most proteins derived from mammals in feed intended for cattle and other ruminants to keep potentially infectious tissue out of cattle feed.⁴

²GAO, *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts*, [GAO-02-183](#) (Washington, D.C.: Jan. 25, 2002).

³21 C.F.R. §589.2000.

⁴Ruminants are animals with four-chambered stomachs, including, but not limited to, cattle, buffalo, sheep, goats, deer, elk, and antelope. For the purpose of this report, unless stated otherwise the term "cattle" refers to cattle and all other ruminant animals and the term "cattle feed" refers to feed for cattle and other ruminant animals.

This report focuses on FDA's implementation and enforcement of the animal feed-ban rule, which many industry and consumer groups consider the most important firewall against the introduction and spread of BSE in the United States.

Under the feed-ban rule, FDA requires firms to (1) label feed and feed ingredients that contain or may contain most proteins from most mammals (referred to hereafter as prohibited material) with a cautionary statement that reads "Do not feed to cattle or other ruminants," (2) have procedures to protect against commingling or cross-contamination if they handle both prohibited and nonprohibited material for feed and feed ingredients, and (3) maintain records so that feed and feed ingredients that contain or may contain prohibited material can be tracked from receipt through disposition.⁵ Firms that transport both types of materials also must have procedures to prevent commingling.

FDA's feed-ban rule applies to feed for cattle and other ruminants, such as sheep and goats. The material prohibited for use in cattle feed may continue to be used in pet food and in feed for poultry, swine, horses, and other nonruminant animals.

The feed-ban rule designates a number of cattle- and other animal-derived items as exempt from the ban, and hence allowable in cattle feed. These exempt items include blood and blood products, plate waste, gelatin, and milk and milk proteins.⁶ In addition, poultry litter (a protein source comprised of poultry waste material, bedding, and spilled feed) is allowed in cattle feed. FDA has published, but not taken action on, several advance notices of proposed rulemaking for revising the ban to, among other things, end most of the exemptions and require that feed manufacturers and other such firms use dedicated equipment for cattle feed.

To oversee compliance with the feed ban, inspectors from FDA and the 38 states that have contracts or agreements with FDA periodically inspect firms, using FDA guidance and an inspection form that FDA developed to

⁵The feed-ban rule is based on FDA's authority to regulate food additives. See 21 U.S.C. §§ 321, 348.

⁶Plate waste is discarded meat and other food from institutions, restaurants, and other dining facilities, which is collected by processors, recooked to eliminate bacteria, and used in animal feed as a protein source. Gelatin is made from boiling animal bones, cartilage, tendons, and skin.

document inspection results.⁷ Since 1997, FDA and states have identified and inspected about 14,800 firms that are subject to the feed-ban rule. The types of firms inspected include renderers, protein blenders, feed mills, farms that mix their own feed, feed transporters, pet food manufacturers, and other firms subject to the feed-ban rule.⁸ In 2002, FDA began using a risk-based priority approach to determine which firms to inspect annually. Under this approach, FDA has designated firms that manufacture, blend, and otherwise directly process with prohibited material as the highest risk for potentially exposing U.S. cattle to BSE. Firms that do not process with prohibited material are designated as lower risk. FDA had designated about 570 firms as high risk in fiscal year 2004. FDA assigns a list of high-risk firms for inspection to each of its district offices and gives the district offices some discretion in deciding which lower risk firms to inspect. FDA also negotiates with states over the number of inspections that FDA will pay for under contract. States conduct about 70 percent of feed-ban compliance inspections. When FDA determines that firms are out of compliance, it can issue warning letters, encourage firms to conduct voluntary recalls, or seek court orders to seize feed or feed ingredients. FDA district offices review inspection results for accuracy and enter inspection information into FDA's central data system—the Field Accomplishments and Compliance Tracking System (FACTS)—and periodically post inspection results on FDA's Web site.

Our January 2002 report identified a number of weaknesses in federal BSE prevention and detection efforts.⁹ Regarding the feed ban, we reported that FDA had not promptly taken actions, such as issuing warning letters or reinspecting firms that were out of compliance, to enforce the feed ban and keep prohibited material out of cattle feed. We also reported that FDA's data on inspections were so severely flawed that the agency could not know the extent of industry compliance. We made a number of recommendations to strengthen FDA's enforcement of the feed ban and its oversight and monitoring of compliance inspections.

⁷FDA is responsible for inspections in the 12 states that do not have contracts or agreements with FDA to conduct inspections.

⁸Renderers process animals unfit for human consumption and waste material (carcasses and meat scraps) from slaughterhouses and processors into a protein for animal feed. Protein blenders mix rendered proteins into feed ingredients.

⁹[GAO-02-183](#).

As you requested, this report examines the effectiveness of the actions FDA has taken, since our 2002 report, to ensure industry compliance with the animal feed ban and protect U.S. cattle from BSE. In addition, appendix III provides a chronology of FDA's and USDA's actions in response to the two cases of BSE discovered in North America in 2003.

In conducting our work, we examined in detail 404 inspection reports from fiscal years 2003 and 2004, which we randomly selected from FDA's 18 district offices responsible for inspections in the 50 states. We interviewed FDA district officials in the 18 districts and observed FDA and state investigators conduct 19 inspections in 12 states. The sites were selected to cover a range of firm types and sizes in various geographic locations with concentrations of cattle feeding operations, including dairy cattle. We met with FDA headquarters' officials responsible for procedures and actions taken to (1) oversee and enforce the feed ban, (2) maintain the inspection data system, and (3) propose and analyze regulatory decisions. We also surveyed state agency officials in the 38 states that had contracts or agreements with FDA in fiscal year 2004 regarding their inspection programs, testing of animal feed and feed ingredients, and the training and guidance they received from FDA. The state survey instrument and summary of responses appear in appendix IV. Appendix I contains a detailed description of our scope and methodology. We performed our work from October 2003 through January 2005, in accordance with generally accepted government auditing standards, which included an assessment of FDA's BSE program data reliability and internal controls.

Results in Brief

FDA has taken a number of important actions, as we recommended in our 2002 report, to improve its implementation of the feed ban. FDA developed a uniform format for federal and state inspectors to document inspection results, implemented a new data system that more reliably tracks inspection results, and entered inspection results into the data system in a more timely fashion. FDA also issued guidance and trained its inspectors along with state inspectors on how to conduct BSE inspections. However, we found the following weaknesses in FDA's oversight and enforcement of the feed ban, which continue to limit the effectiveness of this critical BSE firewall and could place U.S. cattle at risk for BSE:

- FDA acknowledges that more firms are subject to the feed ban than the nearly 14,800 that have been inspected to date, but it does not have uniform procedures for identifying additional firms. Because these firms have never been inspected, FDA has no assurance that they are in

compliance with the feed ban. FDA officials told us the agency has asked Congress for more resources, which it plans to use, in part, to support states' efforts to identify and inspect additional firms. We observed one possible approach to help FDA identify additional firms with existing resources: some inspectors wrote down the names of the suppliers and customers of firms during inspections to check against the inventory of active firms. Inspectors do not routinely note such information, however, because FDA's guidance does not instruct them to do so.

- We found that about 2,800 firms had not been reinspected since 1999 or earlier. While those early inspections indicated that most did not process with prohibited material at that time, the firms could have changed their practices over the last 5 years. Our analysis showed that about two-thirds of those firms were farms that fed cattle and did not feed other types of animals; FDA believes such farms are unlikely to change their practices. However, about 400 firms were feed mills, which FDA would consider at high risk of potentially exposing cattle to BSE if they started to use prohibited material. Because firms are not required to notify FDA if they change their operations and begin to process feed using prohibited material, FDA would not target them for annual inspection as high-risk firms.
- FDA's inspection guidance does not include routinely sampling feed intended for cattle, in cases where such tests would be useful, to augment the visual examination of facilities and equipment and review of documents carried out during inspections. According to FDA, the presence of exempt items, such as cattle blood, which are allowed in cattle feed, would negate the value of the tests because the tests cannot distinguish between prohibited material and these exempt items. However, 18 of the 38 states that conduct BSE inspections under agreement with FDA told us they take samples of feed during inspections to test for animal material. State officials told us that tests could confirm the presence of potentially prohibited material in cattle feed at firms that assert they do not use exempt items. Tests would also be useful to confirm the adequacy of procedures for cleaning equipment and vehicles used for both cattle feed and feed with prohibited material. However, FDA began testing bags of feed sold at retail stores and bulk feed sold to cattle feedlots in August 2003. These samples were not taken as part of the compliance inspections and were not selected systematically. According to FDA officials, tests on some of these samples indicated the presence of animal material and the agency was

investigating those test results at the completion of this report. We plan to provide our analysis of FDA's collection, testing, and follow-up of these samples later this year.

- FDA's regulations do not require the cautionary statement—"Do not feed to cattle or other ruminants"—on feed or feed ingredients that contain prohibited material if they are intended for export, although that feed could be intentionally or inadvertently redirected back into feed for U.S. cattle. In addition, the exported feed containing prohibited material could be fed to cattle in other countries and meat from those animals could subsequently be imported into the United States. However, according to FDA officials, FDA cannot require feed intended for export to carry the cautionary statement without a change to the law that governs the export of food and feed.
- Although FDA has procedures for alerting USDA and states when it discovers that cattle may have consumed feed that contains prohibited material, FDA officials told us that they had never given such notification, even though they had identified instances when prohibited material had been used in cattle feed in the past. FDA said that notification was not needed because BSE had not been discovered in a cow born in the United States. However, FDA's position is inconsistent with the purpose of the feed ban—to be a firewall for safeguarding U.S. cattle from the introduction and spread of BSE. On one inspection we observed, an inspector discovered that a firm's process had been allowing prohibited material into cattle feed for nearly a year. The firm voluntarily conducted a recall, but FDA did not alert USDA and the state. FDA maintained that the recall was sufficient; however, USDA officials told us that the department would have tracked the animals that may have been fed contaminated feed and tested them for BSE when slaughtered.
- FDA has not identified or inspected many transportation firms. In addition, inspectors do not routinely review and document firms' procedures for ensuring that the vehicles they use to haul cattle feed are free of prohibited material. Routine review and documentation does not occur in part because FDA's inspection form does not have specific questions to capture that information. Eighty-two of the inspection reports we examined were for renderers, protein blenders, feed mills, and other firms that handled cattle feed and feed ingredients and also processed with prohibited material. Inspectors documented vehicle clean-cut procedures for only 11 of those 82 firms. Research suggests

that cattle can get BSE from ingesting even a small amount of infected material—an amount that could be introduced in feed that was transported in a poorly cleaned vehicle. FDA told us it has requested resources to identify and inspect more transportation firms. However, because thousands of trucks could transport cattle feed, we believe it would be more effective to review and document cleanout procedures and inspect vehicles as part of inspections at feed mills or other firms that use the vehicles to haul their cattle feed or feed ingredients.

In addition to these weaknesses in the feed-ban firewall, we also identified a related issue that needs to be addressed. FDA is reporting information to Congress and the public on industry compliance without providing a full and complete context for that information. That is, FDA reported a 99 percent compliance rate in January 2004. While FDA noted the rate was based on renderers, protein blenders, and feed mills that process with prohibited material, it did not note that the rate was based on inspections of only about 570 firms. Some industry officials have cited that high rate of compliance as support for their position that FDA does not need to strengthen the feed-ban rule. Furthermore, FDA does not include all serious violations in its calculations of compliance on its Web site because it reclassifies firms as “in compliance” once they correct violations, regardless of how long the problem may have existed. In addition, in 42 of the 404 inspection reports that we analyzed in depth, FDA had counted firms as “in compliance” that lacked written procedures to prevent commingling or cautionary statements on feed that contained prohibited material—violations that can result in cattle being fed prohibited material. Because of these concerns and the fact that FDA is still identifying firms subject to the ban—as well as the fact that inspections are largely paperwork reviews without tests to confirm compliance, and some inspections are 5 or more years old—we do not believe that FDA has enough information or enough current information to cite a rate of compliance. Any compliance information FDA cites must be reported in its complete context.

To further strengthen oversight and enforcement of the animal feed ban and better protect U.S. cattle and American consumers, we are making nine recommendations to the Commissioner of FDA, including that FDA develop procedures for identifying additional firms subject to the ban; ensure that it alerts USDA and states when inspectors discover that feed with prohibited material may have been fed to cattle; and develop guidance for inspectors to use tests to verify the safety of cattle feed and confirm the

adequacy of procedures for ridding equipment and vehicles of prohibited material before using them for cattle feed.

In commenting on a draft of this report, FDA said we had conducted a thorough and diligent study. However, FDA believes that the weaknesses we identified are not sufficiently material to place U.S. cattle at risk for BSE and that its risk-based inspection approach assures adequate oversight of the feed-ban rule. We believe that the problems described in this report are serious and that, given the fact that BSE has been discovered in North American cattle, breaches in FDA's oversight of the feed-ban rule place U.S. cattle at risk for BSE. FDA generally disagreed with four of our nine recommendations. FDA did not agree that, among other things, it should use tests as part of compliance inspections, as we recommend, because current tests cannot detect the prions that cause BSE. That is true. However, the existing test can detect animal tissue, and FDA is using it to test samples of bagged feed and feed sold at mills. We believe tests, in conjunction with document review and visual examination carried out during compliance inspections, will give FDA greater assurance that inspection results are accurate. FDA also disagreed with our recommendation that it require firms that process with prohibited material to notify FDA. FDA believes it would need significant additional resources to implement a notification program and said that its current approach of working collaboratively with states gives FDA a good opportunity to learn when firms change to using prohibited material. If there are not significantly more high-risk firms than the approximately 570 firms FDA already knows about, then the cost of implementing this recommendation would be minimal. However, if the number of firms that process with prohibited material is significantly larger, FDA needs to know that. Appendix VI contains FDA's written comments and our detailed response.

Background

BSE and vCJD belong to a family of diseases known as transmissible spongiform encephalopathies (TSE). Other TSEs include scrapie in sheep and goats, chronic wasting disease in deer and elk, feline spongiform encephalopathy in domestic cats, and mink encephalopathy. Currently, no therapies or vaccines exist to treat TSEs and a definitive diagnosis can only be made from a post-mortem examination of the brain. The infective agent that gives rise to TSEs is generally thought to be a malformed type of protein, called a prion, which causes normal molecules of the same type of

protein in the brain to become malformed and eventually results in death.¹⁰ Prions are neither viruses nor bacteria and contain no genetic material—no deoxyribonucleic acid (DNA). Prions cannot be readily destroyed by conventional heat, irradiation, chemical disinfection, or sterilization procedures.¹¹ TSE prions have been found to accumulate in central nervous system tissue—specifically the brain, spinal cord, and eye—and have been found in other body tissues, such as the tonsils and small intestines, of animals and humans. For BSE, the precise amount of infective material needed to cause disease is unknown, but research suggests that it is very small. According to scientific experts in the European Commission, in careful feeding experiments, less than 1 gram of infected brain tissue induced disease in all the recipient cattle.

The original source of BSE is not known with certainty. However, based on available evidence, experts generally agree that the practice of recycling the remains of diseased animals, specifically scrapie-infected sheep, into feed for livestock, including cattle, was responsible for the emergence and spread of BSE in the United Kingdom. In 1986, BSE was first identified in the United Kingdom; and in 1988, that government banned the practice of feeding ruminant-derived protein to ruminants to thwart its spread. The number of new cases of BSE has declined from a high in 1992 of 37,316 to a total of 764 new cases in 2004. BSE has been found in about 189,000 animals worldwide, most of which (about 184,000) were discovered in the United Kingdom. The remaining cases were discovered in 26 countries, including Canada and the United States. Three nations—the United States, Oman, and the Falkland Islands—have only detected the disease in imported animals. The following are the number of reported cases, by region and/or country:¹²

- *Europe.* United Kingdom—184,045; the rest of Europe—5,107;
- *North America.* Canada—4; United States—1;

¹⁰The prion hypothesis is widely, although not universally, accepted. Some scientists believe a virus or other conventional agent, as yet undetected, gives rise to TSEs.

¹¹Under certain laboratory conditions, high temperature, pressure, and caustic chemicals have been shown to deactivate prions.

¹²These data are as of February 1, 2005, for Canada and as of December 2004 for all other regions/countries.

-
- *Middle East.* Oman—2; Israel—1;
 - *Asia-Pacific.* Japan—14; and
 - *South America.* Falkland Islands—1.

In 1996, the United Kingdom reported the first case of the human disease, vCJD. Scientists believe vCJD is linked to exposure to the BSE prion, most likely through consuming beef and beef products infected with BSE.¹³ While scientists and regulatory officials believe that millions of people in the United Kingdom may have ingested BSE-infected tissue, many also believe vCJD is difficult to contract. As of December 1, 2003, 153 cases of vCJD had been reported worldwide, with 143 of these cases in the United Kingdom. The Department of Health and Human Services' Centers for Disease Control and Prevention, which is responsible for surveillance of vCJD, reported that almost all of the vCJD victims had multiple-year exposures in the United Kingdom during the height of the outbreak of BSE-infected cattle—between 1980 and 1996. Most vCJD victims have been young—the average age at death was 28—and half died within 13 months from the time they first showed symptoms.

The first indigenous case of BSE in North America was discovered in Canada in May 2003. (Canada's first infected cow, discovered in 1993, had been imported from the United Kingdom.) A Canadian government investigation concluded that the infected cow discovered in 2003 most likely contracted the disease by consuming feed containing BSE-contaminated ruminant material, probably before Canada imposed its feed ban in 1997.¹⁴ Canadian authorities believe that BSE entered the feed chain through slaughtered and rendered cattle imported from the United Kingdom. In December 2003, an animal infected with BSE was discovered in the United States. According to U.S. authorities, that animal—a dairy cow in Washington State—had been part of a herd of 81 cattle imported from Canada in September 2001. Appendix III describes FDA's and USDA's actions in response to the 2003 discoveries. In January 2005, Canada discovered two more cases of BSE.

¹³Researchers also believe that one probable case of vCJD reported in the United Kingdom was the result of a blood transfusion from an infected donor.

¹⁴Canada implemented its feed ban on the same day that the United States implemented its feed ban.

Following the discovery of the infected cow in the United States, U.S. beef exports dropped precipitously. The United States is currently engaged in discussions with its major trade partners to reestablish beef exports. In October 2004, Japan, previously the largest importer of U.S. beef, agreed in principle to resume imports of certain beef products from cattle slaughtered at 20 months or younger; as of February 11, 2005, the two countries were working out the details of this agreement.

To detect potentially prohibited material in feed, FDA uses a test called “feed microscopy,” which is a visual examination of a sample under a microscope for the presence of animal tissue, such as hair and bone particles. According to FDA officials, when performed by an experienced analyst, the species can sometimes be identified. FDA is evaluating a more sensitive test called “polymerase chain reaction” (PCR), which detects animal DNA and can distinguish ruminant DNA. However, feed containing exempt items (e.g., milk and blood proteins) derived from ruminants would test positive for ruminant DNA using PCR.

When inspectors find violations of the feed-ban rule, FDA can issue warning letters, and firms may conduct voluntary feed recalls. FDA has the authority to take immediate enforcement action, including seeking a court order to seize feed products that violate the feed ban or obtaining a court-ordered injunction ordering a firm to cease operations. Of the 38 states we surveyed, 37 told us they have authority to take action for violations of the feed ban. FDA directs its districts to issue warning letters within 30 workdays—approximately 45 calendar days after the inspection. Warning letters give firms the opportunity to voluntarily take corrective action before FDA initiates enforcement actions.

Under the risk-based priority inspection system that FDA adopted in 2002, FDA and states have focused inspection resources on the following types of firms, which FDA has designated as high-risk for potentially exposing cattle to BSE:

- *renderers* that accept dead ruminant animals and/or the waste materials from beef slaughter facilities;
- *feed mills* that use prohibited material, which can include FDA-licensed mills that handle certain new animal drugs for use in animal feeds and nonlicensed mills that do not handle such animal drugs; and
- *protein blenders* that use prohibited material.

Other firms subject to the feed ban include the following:

- firms that manufacture only pet food;
- firms that transport or distribute animal feed;
- firms that salvage animal feed or pet food; and
- other firms that handle animal feed, including retailers, grocery warehouses, and specialty food companies.

In addition to inspections of high-risk firms, FDA asks states to perform a number of inspections at the lower risk firms under their contracts or agreements with FDA. FDA also performs inspections of some lower risk firms. Table 1 shows the number of firms inspected during fiscal year 2004.

Table 1: Number of Firms Inspected by FDA and States for Compliance with the Feed-Ban Rule, by Firm Type, Fiscal Year 2004

Firm type	Number of firms
Renderers	195
Protein blenders	164
FDA-licensed feed mills	747
Nonlicensed feed mills	2,615
Others ^a	2,285
Total	6,006

Source: GAO's analysis of FDA's online database.

Note: Since many firms engage in more than one activity (for example, a feed mill may also be a protein blender), this analysis makes assumptions about firms' primary activities to avoid counting firms in more than one category.

^aOther firm types include cattle feeders, transporters, pet food manufacturers, and retail establishments.

Our 2002 report found that

- FDA was not acting promptly to compel firms to keep prohibited materials out of cattle feed and to label animal feed that cannot be fed to cattle;

-
- FDA's data on feed inspections was so severely flawed that FDA did not know the full extent of industry compliance;
 - FDA had no clear enforcement strategy for firms that do not obey the feed ban and did not know what enforcement actions states had taken; and
 - FDA had been using inaccurate, incomplete, and unreliable data to track and oversee feed-ban compliance.

A 2001 study by the Harvard Center for Risk Analysis noted that the greatest risk of BSE exposure to cattle in the United States is through mishandling, mislabeling, or contaminating cattle feed.¹⁵ The study developed a simulation model for predicting the number of infected animals that would result from the introduction of BSE into the United States. Using this model, the Harvard study concluded that, if 10 cattle infected with BSE were imported into the United States, only three new cases of BSE would likely occur, on average, and that BSE is virtually certain to be eliminated from the United States within 20 years following its introduction. According to the study, any new cases of BSE would come primarily from industry's failure to comply with the feed ban. A subsequent 2003 Harvard reassessment—following the discovery of the BSE-infected cow in Canada that year—arrived at a similar conclusion.¹⁶

FDA Has Taken Important Steps to Improve Implementation of the Feed Ban

Since our January 2002 report, FDA has changed the way it collects, tracks, and reports inspection data. In April 2002, FDA implemented a uniform inspection form for federal and state inspectors to document inspection results. Although FDA had an inspection form earlier, inspectors were not always completing the required information, and several states did not use FDA's form.

¹⁵*Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States*, Harvard Center for Risk Analysis, Harvard School of Public Health and Center for Computational Epidemiology, College of Veterinary Medicine, Tuskegee University, Nov. 26, 2001.

¹⁶*Evaluation of the Potential Spread of BSE in Cattle and Possible Human Exposure Following Introduction of Infectivity into the United States from Canada*, Harvard Center for Risk Analysis, Harvard School of Public Health, Oct. 31, 2003.

FDA has also issued feed-ban inspection guidance and appointed BSE coordinators in each of its district offices to review inspection forms for completeness.¹⁷ The district BSE coordinators told us that FDA has trained inspectors on using the inspection form and carrying out inspections. Although most states reported that this training was sufficient, a few told us that they had not received training since the late 1990s or were not able to attend training because of state budget constraints. However, in commenting on a draft of the report, FDA officials said that the agency always offers to provide training to states, when requested.

Regarding the data deficiencies we reported in 2002, FDA implemented a newly designed feed-ban database and data entry procedures in its Field Accomplishment and Compliance Tracking System (FACTS) in April 2002. According to our analysis, this new approach and data system are designed to more reliably track feed-ban inspection results. As a result, FDA has a better management tool for overseeing compliance with the feed-ban rule and a data system that better conforms to standard database management practices. Specifically, FDA's new approach makes the following improvements:

- *All firms have unique identifiers.* Inspection records in FDA's data system—including those that were previously missing unique identifiers—now have them, according to our data reliability analysis. Before the new approach, about 45 percent of FDA's feed inspection records lacked information to identify individual firms. As a result, the earlier data could not be used to reliably determine the number of firms inspected, compliance trends over time, or the inspection history of an individual firm. These problems should not occur with FDA's new system.
- *Information is substantially complete and accurate.* FDA has corrected information problems we had identified in our 2002 report, according to our data reliability analysis of the inspections conducted since April 15, 2002. The new FACTS database contains edit checks to detect any incomplete or inaccurate data. Furthermore, FDA's current feed-ban inspection guidance directs district BSE coordinators or their designees to review BSE inspection forms for completeness and accuracy. Previously, headquarters staff had entered the data received

¹⁷FDA's feed-ban inspection guidance, called the *BSE/Ruminant Feed Ban Inspections Compliance Program Guidance*, was issued on October 21, 2003.

from district offices and did not have sufficient knowledge to detect irregularities in the data they were entering. In addition, states that have contracts or agreements with FDA are now using the same inspection forms as FDA. Previously, several states used state-developed forms, which did not always provide comparable information.

- *Data are more timely.* Since April 15, 2002, about 95 percent of inspections with serious violations have been entered into the FACTS database within 45 days of the inspection date, according to our analysis. This rate of entry is a significant improvement over the timeliness of entry rates we reported in 2002. At that time, we found that some inspections were entered into FDA's database 2 or more years after the date of inspection. For such inspections, FDA could not accurately report on firms' compliance with the feed ban and could not clarify inconsistent or conflicting information, or obtain answers to missing information—situations that FDA's new approach should help avoid.

As a result of these improvements, FDA is able to present more reliable feed ban inspection information on its Web site for the approximately 10,000 firms inspected since April 15, 2002, or about two-thirds of the approximately 14,800 firms inspected since 1997. Appendix II provides a detailed description of actions FDA has taken on the recommendations in our 2002 report.

Program Weaknesses Continue to Limit the Effectiveness of FDA's Animal Feed Ban

While FDA has made many improvements to its oversight and enforcement of the feed ban in response to our 2002 report recommendations, we found a number of oversight weaknesses that limit the effectiveness of the ban and could place U.S. cattle at risk for BSE. Specifically, we found that FDA does not

- have a uniform procedure to identify all firms subject to the feed ban,
- require firms to notify FDA if they process with prohibited material,
- routinely use tests to verify compliance with the feed ban,
- alert USDA or states when cattle may have been fed with feed containing prohibited material, and

- adequately overseeing the procedures for cleaning vehicles that haul cattle feed.

Furthermore, we found that cautionary statements are not required on feed or feed ingredients intended for export that contain prohibited materials. In addition, FDA has not been reporting BSE inspection results to Congress and the public in a full and complete context.

FDA Does Not Have Uniform Procedures to Identify Additional Firms Subject to the Feed- Ban Rule

When the feed ban took effect in 1997, FDA first focused on identifying as many firms as possible that were subject to the ban. As of September 30, 2004, FDA officials had identified approximately 14,800 firms that are subject to the feed ban (see table 2). That is about 4,200 more firms than the 10,576 firms FDA had identified approximately 3 years earlier. FDA officials acknowledge that the agency has not identified all firms subject to the feed-ban rule.

Table 2: Number of Firms FDA Has Identified that Are Subject to the Feed Ban, by Firm Type, as of the End of Fiscal Year 2004

Firm type	Number of firms
Renderers	249
Protein blenders	281
FDA-licensed feed mills	1,061
Nonlicensed feed mills	4,922
Others ^a	8,252
Total	14,765

Source: GAO analysis of FDA's online database.

Note: Since many firms engage in more than one activity (for example, a feed mill may also be a protein blender), this analysis makes assumptions about firms' primary activities to avoid counting firms in more than one category.

^aOther firm types include cattle feeders, transporters, pet food manufacturers and retailers.

FDA has identified firms by reviewing

- its list of firms that manufacture feed that contains certain new animal drugs; FDA knew about these firms because it requires them to be licensed and because it has certain regulatory responsibility over these firms.

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- a list of the firms or individuals that USDA has identified as violating USDA's and FDA's requirements with respect to chemical and drug residues in animals slaughtered for human consumption.¹⁸
 - lists of firms that states identified. For example, 27 of the 38 states we surveyed register renderers, 28 register protein blenders, and 34 register feed mills that FDA has not licensed, and provide this information to FDA during meetings to set up annual inspection plans.
 - membership lists of industry associations, such as the National Renderers Association.

In addition, FDA officials told us that FDA districts have used multiple approaches, including looking through telephone books to identify the names of additional firms. However, FDA has not developed a systematic approach for identifying additional firms subject to the feed ban. For example, FDA does not have an approach for identifying additional nonlicensed feed mills in states that do not provide that information. FDA also acknowledged that it has identified only a small percentage of the thousands of transportation firms that may haul cattle feed. Moreover, in commenting on a draft of this report, FDA told us that there are an estimated 1 million businesses (e.g., dairy farms feedlots, and other facilities) that feed cattle and other animals. FDA also told us that it does not consider farms that mix their own feed or feed cattle as well as other animals as low risk. However, FDA does not have a strategy for ensuring that this industry sector is in compliance with the feed-ban rule.

We observed one approach for expanding the number of firms subject to the feed ban: some FDA and state inspectors we accompanied on firm inspections wrote down the names of the firm's suppliers and customers during the inspection and checked these names against FDA's inventory of firms to help identify additional firms. According to officials in one district where we observed this practice, they inspect these additional firms as resources allow. However, FDA does not have guidance for inspectors to do this routinely, and we observed other inspectors who did not record the names of firms' suppliers and customers. The approach we observed was one that may be largely applied with existing resources. Congress provided FDA with an additional \$8.3 million in the fiscal year 2005 budget, which

¹⁸USDA discovers these violations in tests and visual examinations at meatpacking plants.

FDA officials told us would be used, in part, to fund states' efforts to identify and inspect additional firms.¹⁹

FDA Does Not Require Firms to Notify the Agency if They Process with Prohibited Material

Under FDA's risk-based inspection system, FDA's goal is to annually inspect all renderers, feed mills, and protein blenders that process with prohibited material—about 570 firms—and to inspect a number of other firms that FDA considers lower risk. The number of other firms varies according to the inspection resources available. As previously stated, in total, FDA and states inspected 6,006 firms in fiscal year 2004. However, once FDA has inspected a firm and determined that it does not process with prohibited materials, FDA may not reinspect that firm for many years. In the interim, FDA does not know whether the firm has changed operations and now processes prohibited materials because it does not require firms that do so to notify the agency. FDA and state agencies only learn of a change in operations if they inspect the firms. Without a requirement to notify FDA, these firms are not annually inspected to monitor for compliance with the feed ban, as are other high-risk firms.

We found that 2,833 or about 19 percent, of these firms FDA has identified as subject to the feed-ban rule have not been reinspected in 5 or more years. These firms include

- 1,224 farms that fed ruminant animals;
- 846 farms that mixed their own feed;
- 377 feed mills; and
- 386 other types of firms, such as distributors and retailers.

According to FDA officials, of these four types of firms that have not been reinspected, about 2,100 or two-thirds are farms, which FDA believes are not likely to change their practices. However, feed mills, which account for about 400 of the firms, would be classified as high risk if they process with prohibited material.

¹⁹FDA officials said this funding would be used for additional state and federal inspections, inspector training, industry outreach, and to improve FDA's ability to respond to problems found during BSE inspections.

FDA officials also believe that the number of firms processing with prohibited material is declining and that in all likelihood firms that have not been inspected for a number of years would not change their practices and start doing so. As FDA pointed out, firms may decrease their use of prohibited material because of the requirement that they maintain records sufficient to track all receipt, processing, and distribution of that material. Nonetheless, some firms that did not use prohibited material when they were last inspected may begin to use that material in processing their feed.

FDA officials told us that they have considered options for identifying firms that process feed with prohibited material, including requiring those firms to be licensed. The officials noted, however, that some firms may not comply with a notification requirement; thus, FDA would still not know about all high-risk firms, and it would incur the additional costs of overseeing the notification requirement.

FDA Does Not Routinely Sample Feed and Feed Ingredients during Inspections for Analysis to Verify Compliance with the Feed Ban

While FDA inspection procedures include guidance for reviewing firm documents and procedures, examining their invoices, and inspecting facilities and equipment, they do not include guidance on when samples should be taken and tested. For example, the feed-ban inspection guidance does not instruct inspectors to routinely sample cattle feed to verify firms' claims that they do not use prohibited materials or exempt ingredients, or to ensure that firms' cleanout and flushing procedures to prevent commingling are followed and are effective.

We recognize that the usefulness of testing is limited at firms that use exempt items—cattle and other ruminant blood, milk proteins, poultry litter, and plate waste—as ingredients in cattle feed. FDA officials told us that they did not want to routinely test samples at firms during inspections because the tests would likely have many false positives as a result of the exemptions. Consequently, officials believed testing would not use resources wisely.

However, in 9 of the 19 inspections we observed, inspectors could have used tests to verify feed-ban compliance because the firms claimed they did not use any animal-derived exempt items. Even in these instances, where tests would be beneficial, inspectors did not sample the feed. For instance, inspectors did not take samples to confirm the adequacy of cleanout procedures at firms that use nondedicated production facilities to manufacture cattle feed but do not use any exempt materials. FDA's feed-ban inspection guidance allows inspectors to draw samples at their

discretion, but FDA officials told us that inspectors rely on their judgment of whether the cleanout procedures appear to be adequate and rarely use testing to verify their assessment. FDA officials did not give us a clear reason why they would not advise testing in situations where tests would be useful to help confirm compliance.

Some states have also done significant testing that FDA could use to verify compliance with the feed ban but do not provide their test results to FDA, although that information could give FDA a more complete picture of feed ban compliance. In response to our survey, 18 of the 38 states that have agreements with FDA to conduct feed-ban inspections told us they had collected and tested over 1,500 feed samples during 2003.²⁰ For example, according to a North Carolina Department of Agriculture official, the state collected and tested 738 samples; and, according to a Kansas Department of Agriculture official, the state collected and tested 94 samples. In these states, if the tests find what appears to be prohibited material, the states followed up with the firms to determine what ingredients they used. According to the officials, no contaminated cattle feed was found. In California, which collected and tested about 100 samples, officials found tests to be useful for demonstrating to cattle feed manufacturers the difficulties of cleaning equipment that has been used for prohibited material. FDA and state agency officials told us that most California feed firms have switched to using dedicated equipment for cattle feed. Eleven of the 18 states share test results with FDA, but FDA does not use these results to verify industry compliance with the feed ban.

In August 2003, FDA instructed its districts to begin testing finished feed and feed ingredients, such as bags of feed sold at retail stores and bulk feed sold to cattle feedlots. These tests were not taken in conjunction with feed-ban compliance inspections. FDA inspectors took 660 samples nationwide. The samples were submitted to FDA regional laboratories for analysis, where analysts used feed microscopy. Although in its instructions to districts for the collection effort, FDA called the tests “a method to monitor for compliance with” the feed ban, FDA officials told us that the test results could not be the sole basis for enforcement action at individual firms because microscopic analysis cannot distinguish prohibited bone and tissue from exempted material. Nonetheless, the officials also told us the testing gives FDA further assurance of industry’s compliance with feed ban.

²⁰States reported on a 12-month time period, which could have been the calendar year, federal fiscal year, or state fiscal year.

Because FDA did not use an approach that allows it to generalize the results, the test results cannot be used as assurance of industry compliance. In fact, because FDA did not provide instructions on how to randomly select firms for sampling and how to take a random sample of feed at the firms, the results cannot even help confirm compliance by the stores, feedlots, and other firms where the samples were taken. In initiating this effort without a sampling plan, FDA wasted its already limited inspection resources. FDA has committed resources to collect and analyze 900 additional samples in fiscal year 2005. With the same resources, FDA could have developed a sample design that would have allowed it to generalize the test results to industry.

FDA officials told us the agency would have to conduct an investigation to determine whether an enforcement action was warranted. FDA provided us some information on test results for the 660 samples that were taken and analyzed. The data showed 145 potential violations, including 8 that FDA's laboratories originally classified as serious. About one-third of the 145 samples with potential violations were of cattle feed. Several of those samples had evidence of mammalian matter. Without more information, we could not determine whether the cattle feed contained exempt items or prohibited material. As of February 2005, FDA was in the process of gathering the information we requested from its district offices on the results of its investigation of the 145 potential violations and what, if any, enforcement actions were taken based on the tests and follow-up investigations. We plan to provide our analysis of FDA's collection, testing, and follow-up of these samples later this year.

The Cautionary Statement Is Not Required on Feed Intended for Export

Animal feed and feed ingredients containing prohibited material (including material from rendered cattle) are not required to be labeled with the cautionary statement, "Do not feed to cattle or other ruminants," when that material is intended for export. Shipping containers for such material, however, must be labeled that they are for export only; and, if prohibited material is put back into domestic commerce, the containers must be relabeled with the cautionary statement.

Not placing the warning label on exported feed poses a potential risk to U.S. and foreign cattle and consumers from two perspectives. First, feed with prohibited materials could be intentionally or inadvertently redirected into feed for U.S. cattle if firms fail to add the cautionary label to the product that they had initially intended to export. Second, exported feed containing prohibited material could mistakenly be fed to cattle that are

subsequently imported into the United States or whose meat and other products are imported into the United States.

We observed one situation where a problem could occur because a cautionary statement was not on an exported product. One firm we visited processed fishmeal, which is normally considered a safe ingredient for cattle feed. However, this plant processed the fishmeal on the same equipment it used for prohibited materials. If it were sold domestically, the fishmeal would have to be labeled with the cautionary statement because it is potentially contaminated with prohibited materials. However, the product was shipped to overseas customers without the cautionary statement. Because the fishmeal was not labeled, and fishmeal would not be expected to contain prohibited material, customers could unwittingly mix the fishmeal with other ingredients for their cattle. The FDA inspector did not document in the inspection report which countries were sent the fishmeal. When we asked FDA officials about this situation, they were concerned only about whether feed intended for export was actually being diverted to domestic cattle, a situation that they believed was unlikely to occur because FDA rules prohibit it. However, according to the report by the international panel of experts on BSE convened by USDA, the United States has an obligation to act responsibly toward its global neighbors when exporting feed and feed ingredients.

FDA officials told us that FDA cannot require the cautionary statement on feed intended for export without a change to the Federal Food, Drug, and Cosmetic Act.²¹ Under that act, animal feed intended for export only cannot be deemed to be adulterated or misbranded if it (1) meets the foreign purchasers specifications, (2) is not in conflict with laws of the country to which it is intended for export, (3) is labeled on the outside of the shipping package that it is intended for export, and (4) is not sold or offered for sale in domestic commerce.

²¹An attorney with FDA's Office of the Chief Counsel said that FDA could require a cautionary statement only if the absence of such a statement would cause the feed to be in conflict with the laws of the importing country. See 21 U.S.C. § 381.

FDA Did Not Alert USDA or State Regulatory Authorities When It Learned That Cattle Feed Containing Prohibited Material Was Marketed

When an FDA district office learns that ruminant animals may have been fed contaminated feed, the feed-ban inspection guidance directs the district office to oversee efforts to appropriately dispose of the contaminated feed and to ensure that the animals that had consumed this feed are not slaughtered for human food or other animal feed. The guidance also advises FDA to consider coordination with USDA and the affected states.

While FDA districts have monitored voluntary recalls of feed that did not comply with the feed ban, they had not been alerting USDA or state departments of agriculture when they learned that such feed had been given to cattle and other ruminants—in some cases for an extensive period of time. FDA district and headquarters officials responsible for the feed-ban program were not aware that the guidance instructed FDA to alert USDA and states.

In our observations at inspections and our review of inspection records, we found the following instances in which FDA did not alert USDA or state authorities or take further action.²²

- A producer of cattle, hogs, and goats had inadvertently fed salvaged pet food containing prohibited materials to goats, which are ruminants.²³ We observed the mislabeled feed in a March 2004 inspection. The feed mill that manufactured and sold the feed had not labeled the salvaged pet food with the required cautionary statement “Do not feed to cattle or other ruminants.” Shortly after this discovery, the firm recalled the misbranded feed. In April 2004, a state feed inspector found out about the misfed animals from the feed mill, not from FDA, and alerted his state program managers. The state contacted FDA, and after determining that FDA did not intend to take action beyond issuing a warning letter, the state seized and destroyed the animals in May 2004 under state authority to prevent the meat from entering the food supply. FDA did not alert the state or USDA and did not issue the warning letter to the feed mill until June 2004.

²²USDA’s Animal and Plant Health Inspection Service has the authority to seize and destroy cattle and compensate producers for the cattle.

²³Salvaged pet food containing prohibited materials must be labeled with the cautionary statement.

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- A feed mill had inadvertently contaminated cattle feed with prohibited material. The firm had made a mistake in designing and placing equipment in the manufacturing process, which allowed spilled feed containing prohibited material to become commingled with ingredients used to make cattle feed. We observed this problem during an April 2004 inspection. FDA issued a warning letter in June 2004 demanding that the firm correct the violations; the firm also conducted a voluntary recall of the feed in June. Because the mill operated with this flawed system for about 1 year before the discovery, potentially contaminated feed was marketed and sold for cattle feed for that period of time. FDA did not contact USDA or state authorities to alert them that cattle had consumed the feed.
 - A feed mill did not clean mixing equipment and transportation vehicles used for processing and transporting feed containing prohibited and nonprohibited materials. The firm also failed to properly label feed containing prohibited materials with the required cautionary statement and did not maintain sufficient records for tracking the sale of cattle feed to its customers, as FDA requires. We identified these problems during our review of inspection reports. The inspection occurred in March 2003. The firm corrected the violations and recalled all cattle feed that had not yet been consumed in March 2003. FDA issued a warning letter to the firm in May 2003 and took no further action.

When we discussed these findings with FDA headquarters officials, they told us they were not familiar with the guidance recommending this communication. As a result, FDA, USDA, and state authorities had not assessed the health risk to humans and the animals that may have ingested that feed and may not have taken sufficient action to prevent those cattle and other ruminants from entering the human food or animal feed supply. The FDA officials said they had not considered coordinating with USDA and state officials but that USDA and the states were notified of the recalls because the recalls are posted on the FDA Web site. However, we found that the posted recall notices do not include information on whether, or for how long, cattle or other ruminants had been given the contaminated feed. Furthermore, FDA officials asserted that no action was needed beyond a recall in these incidents because BSE has not been discovered in a cow born in the United States. According to the officials, the meat would not make people ill and the feed would not make cattle ill. Before this report was issued, these same FDA officials told us that in the future, FDA will alert USDA and states when cattle may have consumed prohibited feed. USDA officials told us that they were not aware of these three incidents.

They said that, had they known, USDA would have tracked the animals and tested them for BSE when they were slaughtered.

FDA Has Limited Assurance That Vehicles Used to Haul Cattle Feed Comply with the Feed Ban

According to FDA's feed-ban rule, transportation firms that haul prohibited material and use the vehicles to haul feed or feed ingredients for cattle must have and use procedures to prevent commingling or cross-contamination. The procedures must provide for cleaning out the vehicles or other adequate preventative measures. Research suggests that cattle can get BSE from ingesting even a small amount of infected material—an amount that could be introduced in feed that was transported in a poorly cleaned vehicle. As part of an inspection of transportation firms, inspectors review the adequacy of these procedures, but the inspection form does not prompt them to do so during inspections of other types of firms. The following two problems impede the effectiveness of FDA's current procedures:

- FDA has not identified and does not inspect many transportation firms. According to FDA officials and transportation data, thousands of independent truckers, large and small trucking companies, and rail companies may carry cattle feed and feed ingredients. FDA officials told us that it would be virtually impossible to identify and inspect all of these firms, given its limited resources. However, FDA agrees that transportation compliance is important. In commenting on a draft of this report, the agency noted that it is planning to increase oversight of transportation firms based on FDA's assessment of compliance and risk in this industry sector.
- Inspecting transportation firms at their home base would not ensure that the required procedures are being used and that the nearly 200,000 large trucks that haul animal feed would be clean at the time they picked up cattle feed, in part, because vehicles that carry prohibited material may also carry cattle feed and other loads in succession before returning to their home base. For example, at an inspection of one high-risk protein blender, we observed an FDA inspector talking with an independent trucker who had dropped off a load of cattle feed ingredients, was picking up prohibited materials at the protein blender, and was scheduled later to pick up a load of corn, which could be used in cattle feed. The trucker explained that if he saw anything in the truck between loads, he would climb in and sweep the material out with a broom; if he did not see anything, he did not sweep out the truck between loads. The trucker also said it would be extremely difficult to

find washout facilities to clean the truck between loads while on the road.

Consequently, we believe that it would be more effective to require FDA and state inspectors to review and document procedures that feed mills and other firms use to ensure that the vehicles they use to haul cattle feed and feed ingredients are free of prohibited material as part of their inspections at feed mills and other firms. During our observations of inspections, we found that some FDA and state inspectors were already doing so. However, our observations and analysis of inspection reports showed that the inspectors did not routinely do so and did not uniformly report on the adequacy of the firms' procedures for preventing the introduction of prohibited material. We believe that inspectors were overlooking the adequacy of firm's procedures to ensure the safe transport of cattle feed because the BSE inspection form does not have any questions to capture that information. Specifically, 82 of the 404 inspection reports we reviewed were for renderers, protein blenders, feed mills, and other firms that processed with prohibited material and handled cattle feed and feed ingredients. We found that inspectors had documented the required cleanout procedures for transportation equipment at only 11 of these 82 firms. Without requiring inspectors to uniformly review and document vehicle cleaning procedures, FDA has insufficient assurance that the vehicles are safe to carry cattle feed and feed ingredients.²⁴

FDA Does Not Fully Report BSE Inspection Results

In January 2004, FDA's Deputy Commissioner testified that inspectors "at least annually, targeted BSE inspections of 100 percent of known renderers, protein blenders, and feed mills processing" with prohibited material. He testified that compliance by those firms was "estimated to be better than 99 percent." Subsequently, some industry officials claimed that overall compliance with the feed ban is nearly 100 percent and used that figure to support their claim that the feed ban does not need to be

²⁴These steps take on added importance, given the Department of Transportation's recent proposed rule under the Sanitary Food Transportation Act. In the preamble to the proposed rule, the department stated that it, along with USDA and FDA, had concluded that the expertise for ensuring the safety of the food supply, including transportation, lies with USDA and FDA and that implementation of a food transportation safety program under the Department of Transportation would be unnecessarily duplicative. The proposed rule would incorporate USDA and FDA guidance on the transportation of food. 69 Fed. Reg. 76423 (Dec. 21, 2004).

strengthened. However, as noted earlier, those groups are comprised of about 570 firms—approximately 4 percent of the firms in FDA's inventory.

In addition, FDA periodically publishes compliance information on its Web site for all industry segments. This information has also been used to cite high industry compliance. However, FDA and industry do not have a basis for citing a compliance rate for a segment of firms subject to the feed ban or industrywide because there are too many unknowns. Specifically, FDA does not know the status of compliance for firms that

- have never been inspected,
- have not been reinspected in 5 or more years, and
- may have started to process with prohibited materials since their last inspection.

Furthermore, as we previously discussed, because FDA does not routinely sample feed to confirm compliance, inspection results are largely based on a review of paper documents and a visual inspection. All these concerns apply to compliance information FDA reports to Congress and the public on its Web site.

Additionally, our analysis of inspection reports also disclosed that FDA was not including all serious violations in its calculation of the compliance rate because it reclassified firms as “in compliance” once they correct violations, regardless of how long the problem may have existed.

Finally, we found that FDA has classified 42 firms as having less serious violations that it counted as “in compliance” with the feed ban. Inspectors reported that 18 of these firms failed to include a cautionary statement on feed containing prohibited materials. Although FDA's feed-ban inspection guidance designates the lack of a cautionary statement as a serious violation, and lack of such a statement should result in the feed being deemed misbranded under the Federal Food, Drug, and Cosmetic Act, FDA excluded the violations at these firms from its calculation of the compliance rate. Inspectors also reported that the remaining 24 firms had procedures for preventing commingling but did not have these procedures in writing. FDA's guidance designates the lack of written procedures as a less serious violation, but we believe these violations should be classified as serious. Without written procedures, FDA has no assurance that the firms consistently take the necessary steps to prevent commingling. FDA

officials told us that the guidance is advisory and therefore gives the agency the discretion to reclassify the violations based on its review.

Conclusions

Diligent FDA oversight and enforcement of the feed ban is essential, not only because of the potential threat to public health but also because of the economic impact on the cattle and beef industry; this impact was clearly demonstrated by the sharp drop in U.S. beef exports after one infected cow was discovered in 2003. The ongoing discussions and agreements to reopen beef export markets could be derailed if more cattle were discovered with BSE.

FDA has taken positive steps since our 2002 report. Today FDA can say with greater confidence that it has more timely and reliable inspection data. Also, the risk-based system FDA has adopted to target inspection resources on high-risk firms will increase the likelihood that firms inspected annually will remain in compliance with the feed ban.

FDA's processes, however, still have considerable room for improvement. FDA does not have uniform procedures for identifying additional firms that are subject to the ban but have never been inspected or for learning about firms that change their practices and begin to handle prohibited material. Furthermore, because inspectors are not using tests optimally—to help confirm, when appropriate, that cattle feed, production equipment, and transportation vehicles are free of prohibited material—FDA is limiting its ability to assure that firms are in compliance with the feed ban and that cattle feed is safe. Additionally, FDA is not taking advantage of state test results to provide greater assurance that industry is adhering to the feed ban and is not using its own program for sampling finished feed and feed ingredients in a manner that will allow it to project test results.

Moreover, the lack of a requirement for warning labels on feed and feed ingredients intended for export that contain prohibited material, creates opportunities for having the material fed to domestic or foreign cattle, either intentionally or inadvertently. As the international group of BSE experts convened by USDA pointed out, the United States has an obligation to act responsibly toward its global neighbors when exporting feed and feed ingredients.

Especially troubling was our discovery that FDA did not alert USDA and state authorities when it became aware that cattle had been given feed that contained prohibited material. FDA, and its key partner, USDA, together

provide critical firewalls that the federal government has in place to protect U.S. cattle and consumers. In addition, the lack of notification was contrary to FDA's own guidance and FDA's inaction prevented USDA and states from being able to make an informed decision on how to respond to the discovery that cattle had consumed prohibited material.

Given these weaknesses and the fact that FDA does not include all violations in its estimates, we believe FDA is overstating industry's compliance with the animal feed ban and understating the potential risk of BSE for U.S. cattle in its reports to Congress and the American people. Despite the problems in FDA's calculation, some in the feed industry claim that overall compliance with the feed ban is nearly 100 percent—a claim that FDA's compliance information does not support.

Recommendations for Executive Action

To further strengthen oversight and enforcement of the animal feed ban and better protect U.S. cattle and American consumers, we recommend that the Commissioner of FDA take the following nine actions:

- Develop uniform procedures for identifying additional firms subject to the feed ban.
- Require firms that process with prohibited material to notify FDA. If FDA believes it does not have the necessary statutory authority, it should seek that authority from Congress.
- Develop guidance for inspectors to systematically use tests to verify the safety of cattle feed and to confirm the adequacy of firms' procedures for ridding equipment and vehicles of prohibited material before they are used for processing or transporting cattle feed or feed ingredients.
- Collect feed test results from states that sample feed to help verify compliance with the feed ban.
- Develop a sample design for FDA's inspectors to use for sampling finished feed and feed ingredients that will allow FDA to more accurately generalize about compliance with the feed ban from the test results.
- Seek authority from Congress to require the cautionary statement on feed and feed ingredients that are intended for export and that contain prohibited material.

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- Ensure that USDA and states are alerted when inspectors discover that feed or feed ingredients with prohibited material may have been fed to cattle.
 - Modify the BSE inspection form to include questions inspectors can use to document whether firms that process or handle cattle feed or feed ingredients have procedures to ensure the cleanliness of vehicles they use to transport cattle feed and feed ingredients.
 - Ensure that inspection results are reported in a complete and accurate context.

Agency Comments and Our Evaluation

We provided FDA with a draft of this report for review and comment. FDA stated that our report was thorough and that it recognized the enhancements FDA has put in place in its feed-ban program. However, FDA said the report did not identify material weaknesses to support our position that oversight weaknesses limit FDA's program effectiveness and place U.S. cattle at risk of spreading BSE. FDA believes that its current risk-based inspection approach is adequate to protect U.S. cattle. According to FDA, given the wide variety of firms subject to the feed ban and its resource limitations, it "is obligated to set priorities for inspecting a meaningful subpopulation of these regulated firms." We recognize that FDA has made many improvements, including adopting a risk-based approach for inspections, that have substantially improved its oversight of the feed-ban rule. However, our report identifies significant problems in FDA's oversight that continue to place cattle at risk for BSE. The importance of a strictly enforced feed ban is heightened now that BSE has been found in North American cattle. As Harvard and the international panel of experts pointed out, the feed ban is the most important fire wall against the spread of BSE. Given the problems we identified and the significance of a well enforced feed ban, it is important that FDA improves its feed ban oversight and optimizes its use of resources.

In addition, FDA does not agree with our criticism of its compliance reporting. FDA believes that it provides the inspection results in a transparent, complete, and accurate context. FDA notes that the BSE inspection data posted on its Web site "allows the user to analyze the data, in a multitude of ways, to provide their own contextual reference." Our concern is precisely that the data are being analyzed and interpreted in an erroneous context. Specifically, when FDA and industry used those data to assert a 99 percent compliance rate with the feed ban, they took that

information out of context. While FDA's calculation of compliance by a subset of regulated industries may in fact be quite high, FDA's data are not sufficient to make that projection to all regulated industries. In addition, FDA does not know the status of compliance for firms that have never been inspected or have not been reinspected in years. Nor does it know if previously inspected firms have started using prohibited material. Furthermore, because FDA reclassifies firms from "out-of-compliance" to "in-compliance" on its Web site when the firms correct violations, the information posted on that Web site does not tell the user when serious and/or long-standing violations have occurred. Lastly, inspection results are largely based on a review of paper documents and a visual inspection, with little or no feed testing. Given these data concerns and compliance unknowns, FDA's data should not be used to project industry compliance; and, anytime those data are cited, they should be reported in a complete and accurate context.

Regarding the nine recommendations we make in the report, FDA did not take issue with the need for five and generally disagreed with four. Although FDA noted implementation concerns, it did not take issue on the need for (1) developing uniform procedures for identifying firms subject to the feed ban, (2) collecting test results from the states that sample feed, (3) including a cautionary statement on feed and feed ingredients intended for export, (4) notifying USDA and states when feed or feed ingredients containing prohibited material may have been fed to cattle, and (5) modifying the inspection form to include questions to better oversee the cleanliness of vehicles used to transport cattle feed or feed ingredients.

FDA disagreed with our recommendation that it require firms that process with prohibited material to notify the agency. FDA believes that it is already getting information on changes to firms' practices from states and that requiring an additional notification process would be costly to implement. However, FDA acknowledged that it has generally not identified high-risk feed salvagers and farms that mix their own feed or those that feed cattle as well as other animals. The cost of the notification program will depend on the requirements FDA puts in place. In developing the program, FDA could target the notification to firms that pose a potentially high risk for exposing cattle feed to prohibited material. We believe that FDA should know which firms are high risk and that industry self-reporting is a mechanism that would help the agency identify those firms and help it ensure compliance with the feed ban.

FDA also disagreed with our recommendation to systematically use tests in conjunction with compliance inspections. While we recognize the limitations of current test methodologies, we believe that tests are useful. In fact, states and FDA are currently using these tests on feed. Our recommendation speaks to systematically using these tests where appropriate, to augment inspections, which are largely observation and paperwork reviews. We expanded the recommendation to recognize that FDA may validate other tests in the future.

With respect to our recommendation that FDA develop a sample design for testing finished feed and feed ingredients, FDA disagreed with the need for a sample design that will allow it to more accurately generalize about compliance. FDA stated that tests alone cannot serve as a basis to generalize compliance. We agree that tests that indicate potential violations need to be confirmed, because of the limitations of the current tests. However, FDA is using the test results to identify potential problems, and it tested 660 samples in 2003/2004 and plans to test 900 samples this year. The point of our recommendation is that any testing activity of this magnitude should have a sampling plan.

Finally, FDA believes that it already reports inspection results in a complete and accurate context, as we recommend. We disagree. As noted above, given the data concerns and compliance unknowns raised in this report, FDA's data should not be used to project industry compliance. Anytime those data are cited, they should be reported in a complete and accurate context. FDA also provided technical comments, which we have incorporated into this report, as appropriate. FDA's written comments and our responses are in appendix VI.

We also provided USDA with a draft of appendix III, which summarizes FDA's and USDA's actions in response to the 2003 discovery of BSE in North America, for review and comment. USDA had no comments on the draft appendix.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from the date of this letter. We will then send copies to interested congressional committees; the Secretary of Health and Human Services; the Secretary of Agriculture; the Director, Office of Management and Budget; and other interested parties. We will make copies available to others on request. In

addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please call me at (202) 512-3841. Key contributors to this report are listed in appendix VII.

A handwritten signature in black ink, appearing to read "Robert Robinson". The signature is written in a cursive style with a large initial "R".

Robert A. Robinson
Managing Director, Natural Resources
and Environment

Scope and Methodology

As discussed below, to assess the effectiveness of the Food and Drug Administration's (FDA) actions to ensure industry compliance with the feed ban and protect U.S. cattle from bovine spongiform encephalopathy (BSE), we (1) analyzed 404 inspection reports for BSE inspections performed during fiscal year 2003 and 2004; (2) observed 19 inspections in 12 states that were conducted by either FDA or state inspectors; (3) assessed the reliability of FDA's feed-ban inspection database; (4) interviewed officials at FDA headquarters and district offices, state agencies, and industry associations, as well as reviewed documents provided by these officials concerning oversight of the animal feed ban; and (5) surveyed state agency officials in 38 states.

To assess FDA's oversight, we analyzed BSE inspection records to identify types of firms inspected; types of material processed (prohibited, nonprohibited, or both); oversight of transportation equipment; violations identified during inspections (if applicable); and final inspection classifications. We randomly selected 413 inspection reports from the universe of BSE feed inspections conducted during fiscal year 2003 and fiscal year 2004 (up to February 7, 2004). For each of the 18 FDA districts, responsible for inspections in the 50 states, we randomly selected inspection reports from one state (most FDA district offices cover more than one state). We included all of the 314 high-risk firms that process prohibited materials for the 18 selected states. In addition, we randomly selected 12 other firms that process with prohibited materials; 68 firms that distribute prohibited materials; and 19 firms that do not process or distribute prohibited materials. We examined only 404 of the 413 inspection reports because 9 of the report files that we requested were still open-case files at the time of our review.

To evaluate the inspection process, we accompanied inspectors on 19 BSE inspections of firms in 12 states covered by the feed ban. The sites were selected to cover a range of firm types and sizes in various geographic locations with concentrations of cattle feeding operations, including dairy cattle. The 19 inspections included renderers, protein blenders, feed mills, farms with ruminants and other animals, and pet food manufacturers. Seven of these firms processed or handled only prohibited material, and the remaining 12 processed or handled both types of material. On 12 of the inspections, we accompanied FDA inspectors, and on 7 we accompanied state inspectors.

To assess the reliability of the data FDA uses when reporting industry compliance, we analyzed the agency's database for inspections conducted

on or after April 15, 2002, when FDA implemented its newly designed feed-ban database.¹ Specifically, we analyzed the 9,230 inspection records in this database, as of February 7, 2004. To complete the reliability assessment, we (1) reviewed existing documentation related to the data sources; (2) electronically tested the data to identify obvious problems with completeness, accuracy, or timeliness of data entry; and (3) interviewed knowledgeable agency officials about the data. We determined that the data were sufficiently reliable for purposes of this report.

We interviewed officials or reviewed documents at FDA headquarters and at the 18 FDA district offices that are responsible for overseeing and enforcing the feed ban in the 50 states, maintaining the inspection database system, and proposing and analyzing regulatory decisions. In the 18 district offices, we used a structured interview to uniformly gather information on various issues, such as methods used to identify the universe of firms subject to the feed ban; the process for selecting firms for inspection; training programs for FDA and state inspectors; feed-ban inspection guidance and procedures; the processes for reviewing inspection results, classifying findings, and determining what, if any, enforcement action should be taken; and oversight of contracts and agreements with state agencies that perform BSE inspections. We received information and documentation on FDA's oversight and enforcement of the feed ban from the following specific FDA units: Center for Veterinary Medicine, Office of Management, Office of Surveillance and Compliance; Office of Regulatory Affairs Office of Regional Operations; Center for Food Safety and Applied Nutrition's Office of the Director; and Office of the Chief Counsel. We reviewed various FDA program documents, including the BSE/Ruminant Feed Ban Inspections Compliance Program Guidance; BSE feed inspection form; advance notices of proposed rulemakings to strengthen the feed ban, including public comments; and the reports on the feed samples collected and tested. We also interviewed state agency officials and reviewed documents from the California Department of Food and Agriculture; the Departments of Agriculture of Georgia, Illinois, Kansas, Missouri, North Carolina, and Pennsylvania; and the Texas Feed and Fertilizer Control Service. Lastly, we interviewed officials and reviewed documents from the American Feed Industry Association, the Association of American Feed Control Officials, the National Renderers Association, the Association of Analytical Communities, and the Harvard Center for Risk Analysis.

¹Previously, we reported that FDA has been using inaccurate, incomplete, and unreliable data to track and oversee feed ban compliance ([GAO-02-183](#)).

To understand the role that states play in the feed inspection program, we surveyed state officials in the 38 states that have contracts or other agreements with FDA to perform feed-ban compliance inspections and report the inspection results to FDA.² The survey included questions about the states' inspection programs, testing of animal feed ingredients, and FDA's training and guidance for feed-ban inspections and enforcement. Before implementing our survey, we pretested the questionnaire with state agriculture officials in five states. During these pretests, we interviewed the respondents to ensure that (1) questions were clear and unambiguous, (2) terms were precise, and (3) the survey did not place an undue burden on the staff completing it. We received completed questionnaires from all 38 states surveyed. The state information presented in this report is based on information obtained from this survey and interviews with state officials.

We performed our work from October 2003 through January 2005, in accordance with generally accepted government auditing standards, which included an assessment of data reliability and internal controls.

²At the time of our review, the following states did not have a contract or partnership agreement with FDA to perform and report BSE inspections to the agency: Alaska, Connecticut, Delaware, Hawaii, Louisiana, Maine, Massachusetts, Mississippi, New Hampshire, Rhode Island, South Carolina, and Wyoming.

GAO's Analysis of the Status of Actions on Recommendations to FDA in Our January 2002 Report

Recommendation	Status of actions taken
<p>In order to strengthen oversight and enforcement of the animal feed ban, we recommended that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following actions:</p>	
<p>Develop a strategy, working with the states, to ensure that the information FDA needs to oversee compliance is collected and that all firms-subject to the feed ban are identified and inspected in a timely manner.</p>	<p>FDA (1) developed a new BSE inspection form that provides guidance to FDA and state feed-ban inspectors on how to uniformly and completely document firm's operations and assess compliance, (2) designated a BSE program coordinator in each district office who is responsible for ensuring that inspection reports are accurate and completed timely, and (3) provided training for FDA and state inspectors on conducting and documenting BSE inspections.</p> <p>FDA has not developed a uniform strategy to identify all firms subject to the feed ban or to ensure that all firms are inspected in a timely manner.</p>
<p>Ensure that, as contractors modify the inspection database, they incorporate commonly accepted data management and verification procedures so that the inspection data can be useful as a management and reporting tool.</p>	<p>FDA implemented a newly designed BSE feed-ban database and data-entry procedures designed to more reliably track feed-ban inspection results. The new database, a module of FDA's Field Accomplishment and Compliance Tracking System, contains commonly recognized database management and verification procedures, such as unique identifiers for each inspected firm and edit checks to help ensure that data entered is complete and valid.</p>
<p>Develop an enforcement strategy with criteria for actions to address firms that violate the ban and time frames for reinspections to confirm that firms have taken appropriate corrective actions.</p>	<p>FDA issued feed-ban inspection guidance to FDA and state inspectors and program managers for determining compliance with the animal feed ban and to help ensure that BSE feed inspections and enforcement actions are conducted in a uniform manner and are of high quality.</p>
<p>Track enforcement actions taken by states.</p>	<p>FDA does not plan to track enforcement actions taken by states, as we had recommended. Officials told us that FDA and state enforcement actions would not be comparable because state standards for initiating an action may not be equivalent to FDA standards. As a result, FDA believed that the information would be misleading if presented collectively.</p>

Appendix II
GAO's Analysis of the Status of Actions on
Recommendations to FDA in Our January
2002 Report

(Continued From Previous Page)

Recommendation	Status of actions taken
<p>In order to strengthen inspections of imported products that could pose a risk of BSE, we recommended that the Secretaries of Health and Human Services and of Agriculture, in consultation with the Commissioner of Customs:</p> <p>Develop a coordinated strategy, including identifying resource needs.</p>	<p>FDA hired more than 655 additional food security personnel and increased its port-of-entry food examinations, including imported animal feed that could pose a risk of BSE.</p> <p>As part of the prior notice requirement of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, FDA and the U.S. Customs and Border Protection announced that they have integrated their information systems, which allows FDA staff to more efficiently evaluate and process each import entry.</p> <p>FDA and U.S. Customs and Border Protection signed a memorandum of understanding under which FDA commissions Customs officers in ports and other locations to conduct, on FDA's behalf, investigations and examinations of imported food, including animal feed. Currently, FDA has commissioned over 8,000 Customs officers.</p>
<p>To further help consumers identify foods and other products that may contain central nervous system tissue, we recommended that the Secretary of Health and Human Services:</p> <p>Consider whether the products it regulates, including food, cosmetics, and over-the-counter drugs, should be labeled to advise consumers that the products may contain central nervous system tissue.</p>	<p>FDA does not intend to label these products, as we recommended. Officials told us that that the decision to label products has to be based on science and if the presence of central nervous system tissue poses a human risk, then it should not be allowed as an ingredient in the product.</p> <p>FDA issued an interim final rule in July 2004 that prohibits the use of certain cattle material, including central nervous system tissue from nonambulatory cattle, in human food, including dietary supplements, and cosmetics.</p>

Source: GAO analysis of FDA documents.

GAO's Summary of FDA's and USDA's Actions in Response to the Two Cases of BSE Discovered in North America in 2003

Date	FDA	USDA
May 20, 2003	Canadian government reported that a single cow from Alberta had tested positive for BSE. FDA began working with USDA, other federal agencies, and Canadian officials to gather additional information about this cow, including its location, previous ownership, and records about its feed.	USDA temporarily halted imports of live ruminant animals and most ruminant products from Canada.
May 26, 2003	FDA learned from the Canadian government that rendered material from the BSE-infected cow may have been used to manufacture pet food, some of which was shipped to the United States. FDA notified the U.S. pet food firm that received the feed ingredients and the firm requested that customers who may have purchased the suspect product hold it for pickup by the distributor.	
August 8, 2003		USDA announced it would allow certain ruminant products from Canada to enter the United States under permit. These include boneless beef from cattle under 30 months of age and boneless veal from calves that were 36 weeks of age or younger.
October 31, 2003		USDA announced a proposed rule, published on November 2003, to allow the importation of certain low-risk, live ruminant animals and ruminant products from Canada. USDA released the results of the second Harvard BSE risk assessment. The study found that even if infected animals or ruminant feed material entered the United States from Canada, the risk of BSE spreading within the U.S. herd is low.
December 9, 2003		USDA collected samples from a nonambulatory cow and diverted all potentially high-risk material (central nervous system tissue) from the human food supply and into the animal rendering process.
December 22, 2003		USDA laboratory test results are "preliminary positive" for BSE.

Appendix III
GAO's Summary of FDA's and USDA's Actions
in Response to the Two Cases of BSE
Discovered in North America in 2003

(Continued From Previous Page)

Date	FDA	USDA
December 23, 2003	<p>USDA's Animal and Plant Health Inspection Service (APHIS) notified FDA's Office of Crisis Management that a "presumptive positive" finding of BSE in the Washington cow.</p> <p>FDA activated its Emergency Operations Center and began to implement its BSE Emergency Response Plan. FDA headquarters and district office staff participated in a teleconference with APHIS and Washington State officials to ensure a coordinated response to the incident.</p>	<p>USDA announced a "presumptive positive" finding of BSE.</p> <p>USDA sent a sample from the infected animal to a world reference laboratory in the United Kingdom for final confirmatory testing.</p> <p>APHIS quarantined the cattle herd where the BSE-infected cow last resided and began an epidemiological investigation.</p> <p>USDA's Food Safety and Inspection Service (FSIS) initiated a recall of the over 10,000 pounds of meat from the group of 20 cattle slaughtered on December 9.</p>
December 24, 2003	FDA dispatched several teams of investigators to find any FDA-regulated products that were or could have been made from the infected cow, including animal feed.	
December 25, 2003		The world reference laboratory in the United Kingdom confirms USDA's BSE diagnosis.
December 27, 2003	FDA announced that an estimated 2,000 tons of feed that could contain potentially infectious material from the BSE-infected cow was found before any of it was used to manufacture animal feed. According to FDA, the feed was disposed of in a landfill in accordance with federal, state, and local regulations.	USDA's investigation with Canadian officials indicated that the BSE-infected cow was likely imported from Canada in 2001 and was about 6½ years old.
December 28, 2003		<p>USDA identified 73 other cattle that were imported from Canada in the same shipment with the BSE-infected cow.</p> <p>USDA determined that the recalled meat products had been distributed to Alaska, California, Guam, Hawaii, Idaho, Montana, Nevada, Oregon and Washington.</p>
December 31, 2003		USDA appointed an international team of scientific experts to review its BSE investigation and make recommendations following the completion of the epidemiological investigation.
January 6, 2004		USDA's and Canada's chief veterinary officers held a joint press conference to announce that DNA evidence indicated—with a high degree of certainty—that the BSE-positive cow found in Washington State originated from a dairy farm in Alberta, Canada.

Appendix III
GAO's Summary of FDA's and USDA's Actions
in Response to the Two Cases of BSE
Discovered in North America in 2003

(Continued From Previous Page)

Date	FDA	USDA
January 12, 2004		FSIS issued an interim final rule, effective January 12, 2004, that, among other things, prohibited the use of brain, skull, spinal cord, and other specified tissues of cattle 30 months or older for human food, and required that all nonambulatory animals presented for slaughter be condemned. FSIS also gave notice that it would no longer pass and give a mark of inspection to carcasses and cattle parts selected by APHIS until the sample is determined to be negative.
January 26, 2004	FDA announced that it would be issuing interim final rules to strengthen existing BSE firewalls, including banning a wide range of cattle material from human food, dietary supplements, and cosmetics, and strengthening the 1997 feed ban through an extended list of banned feeding and manufacturing practices.	
February 9, 2004		USDA completed its investigation of the Washington State BSE case.
June 1, 2004		Following the international scientific review panel's recommendation, USDA began an enhanced BSE surveillance program targeting cattle from highest-risk populations, as well as a random sampling of animals from the aged cattle population.
July 14, 2004	FDA requested information and public comment on additional measures that are being considered for strengthening the 1997 feed ban. FDA requested this information because the international scientific review panel convened by the Secretary of Agriculture recommended broader measures than FDA had previously announced it would be issuing as part of an interim final rule, such as banning all mammalian and poultry protein from ruminant feed. FDA issued an interim final rule that prohibits certain cattle material from human food, dietary supplements, and cosmetics.	USDA asks for public comment on additional preventative actions that are being considered concerning BSE, such as implementation of a national animal identification program.
September 30, 2004	FDA announced the availability of industry guidance "Use of Material from BSE-Positive Cattle in Animal Feed."	

Source: GAO analysis of FDA and USDA documents.

Survey of State Agencies



United States General Accounting Office
Washington, DC 20548

Food and Drug Administration BSE Inspection Program: Survey of States with Contracts and Other Agreements with FDA

Introduction

The U.S. General Accounting Office (GAO), an agency of the U.S. Congress, is studying FDA's Feed Inspection program at the request of the Senate Committee on Agriculture, Nutrition, and Forestry.

As part of our study we are surveying states that have contracts with FDA to conduct BSE inspections or who have agreements or arrangements with FDA to share data from their state inspections.

Your cooperation is critical to our ability to provide current and complete information to the Congress. You will be notified when the report is issued and you will be able to request a free copy of the report at that time.

If you have any questions, please contact :

John Smith
GAO Atlanta Field Office
(404) 679-1923 or smithj@gao.gov

or
Natalie Herzog
GAO Atlanta Field Office
(404) 679-1889 or herzog@gao.gov

Filling Out Your Questionnaire

In order to ensure that your data are entered accurately, please use blue or black ink to enter your answers. Return the original copy of the completed questionnaire to us.

We suggest you keep a copy of your completed questionnaire for your records.

Returning Your Questionnaire:

Please use the enclosed pre-paid, pre-addressed Fed Ex envelope and return your completed questionnaire to:

John Smith
GAO Atlanta Field Office
2635 Century Parkway, Suite 700
Atlanta, GA 30345

Please return your completed questionnaire to us by June 25, 2004.

Section I: Reporting Year Used for BSE Inspections

Several questions ask for data from 2003 and for projected data for 2004. In answering these questions, please use the year that your state uses in planning, scheduling, monitoring, and reporting the BSE inspections in your state.

1. What is the year you used for planning, scheduling, monitoring and reporting to FDA the data from BSE inspections done in your state in 2003?

Reporting Year Used for Inspections in 2003: (Please check one.)

- N = 38**
- 18 (1) Federal Fiscal Year
47.4%
- 0 (2) Calendar Year
0.0%
- 12 (3) State Fiscal Year → Please provide months and days below.
31.6%
- From: (Month/Day) _____
- To: (Month/Day): _____

- 8 (4) Other → Please provide months and days below.
21.0%
- From: (Month/Day) _____
- To: (Month/Day): _____

2. What is the year you are using for planning, scheduling, monitoring and reporting to FDA the data from BSE inspections being done in your state in 2004?

Reporting Year Used for Inspections in 2004: (Please check one.)

- N = 37**
- 17 (1) Federal Fiscal Year
45.9%
- 1 (2) Calendar Year
2.7%
- 13 (3) State Fiscal Year → Please provide months and days below.
35.1%
- From: (Month/Day) _____
- From: (Month/Day) _____
- 6 (4) Other → Please provide months and days below.
16.2%
- From: (Month/Day) _____
- To: (Month/Day): _____

Section II: Your State's BSE Inspection Program

3. Does your state have laws and regulations covering the adulteration and misbranding of animal feed? (Please check one.)

N = 38

37 (1) Yes
97.4%

1 (2) No
2.6%

4. Does your state have laws and regulations specifically covering labeling of animal feed for BSE? (Please check one.)

N = 38

14 (1) Yes → **Skip to Question 6**
36.8%

24 (2) No
63.2%

5. Does your state plan to enact a law or regulation that would require labeling of animal feed for BSE?

N = 24

5 (1) Yes
20.8%

3 (2) No
12.5%

16 (3) Uncertain
66.7%

6. Does your state have laws and regulations specifically covering BSE animal feed inspections? (Please check one.)

N = 38

7 (1) Yes
18.4%

31 (2) No → **Skip to Question 8**
81.6%

**Appendix IV
Survey of State Agencies**

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7. Has your state referenced any of the following in your state laws and regulations? *(Please check all that apply.)*

N = 7

- 14.3% ⁽¹⁾ Referenced all of: American Association of Feed Control Officials (AAFCO) Model Regulation.12, Certain Mammalian Proteins Prohibited in Ruminant Feed
- 0.0% ⁽²⁾ Referenced part of: American Association of Feed Control Officials (AAFCO) Model Regulation.12, Certain Mammalian Proteins Prohibited in Ruminant Feed
- 85.7% ⁽³⁾ Referenced all of: 21 CFR § 589.2000 Animal Proteins Prohibited in Ruminant Feed
- 0.0% ⁽⁴⁾ Referenced part of: 21 CFR § 589.2000 Animal Proteins Prohibited in Ruminant Feed
- 14.3% ⁽⁵⁾ Referenced definitions used in either of the above.
- 14.3% ⁽⁶⁾ Other
(Please provide citation.)

8. Does your state plan to reference any of the following in future state laws or regulations? *(Please check all that apply.)*

N = 29

- 36.7% ⁽¹⁾ Do not plan to reference any of the following.
- 34.5% ⁽²⁾ Plan to reference all of: American Association of Feed Control Officials (AAFCO) Model Regulation.12, Certain Mammalian Proteins Prohibited in Ruminant Feed
- 6.9% ⁽³⁾ Plan to reference part of: American Association of Feed Control Officials (AAFCO) Model Regulation.12, Certain Mammalian Proteins Prohibited in Ruminant Feed
- 24.1% ⁽⁴⁾ Plan to reference all of: 21 CFR § 589.2000 Animal Proteins Prohibited in Ruminant Feed
- 6.9% ⁽⁵⁾ Plan to reference part of: 21 CFR § 589.2000 Animal Proteins Prohibited in Ruminant Feed
- 24.1% ⁽⁶⁾ Plan to reference definitions used in either of the above.

9. Do your state laws or regulations give you authority to inspect transportation firms for compliance with the BSE feed ban? *(Please check one.)*

N = 36

- 58.3% ⁽¹⁾ Yes
- 41.7% ⁽²⁾ No

10. Do your state laws or regulations require firms that handle both prohibited and non-prohibited materials use dedicated equipment? *(Please check one.)*

N = 38

- 0.0% ⁽¹⁾ Yes
- 100.0% ⁽²⁾ No → *Skip to Question 12*

11. Does your state's requirement for dedicated equipment for prohibited and non-prohibited materials apply to transportation firms? *(Please check one.)*

N = 0

- ⁽¹⁾ Yes
- ⁽²⁾ No

12. In developing your BSE Inspection Workplan, how do your state and FDA determine the number and type of firms each of you will inspect? *(Please use the space below, or, if you prefer, attach a separate sheet with your answer.)*

N = 38

35 (92.1%) of the respondents provided an answer.

**Appendix IV
Survey of State Agencies**

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13. During the year, how often does your state discuss your BSE Inspection Workplan with FDA staff? *(Please check one.)*

N = 38

- 15.8% ⁶ (1) Weekly or more frequently
- 10.5% ⁴ (2) Monthly
- 23.7% ⁹ (3) Quarterly
- 2.6% ¹ (4) Annually
- 39.5% ¹⁵ (5) As needed, based on changes to the feed ban, regulations or guidance
- 7.9% ³ (6) Other *(Please specify.)*

14. What type of arrangement(s) did your state have with FDA during 2003 and how many inspections were done under each type of arrangement? *(Remember to use your state's reporting year.)*

N = 38 **For 2003:** *(Please check all that apply and fill in number of inspections where checked.)*

- 92.1% (1) A contract with FDA to perform BSE inspections and report results to FDA

Number of BSE inspections done under contract:	Total: ~3100
--	---------------------
- 7.9% (2) A partnership or cooperative agreement with FDA to perform BSE inspections and report results to FDA

Number of BSE inspections done under contract or partnership:	Total: ~200
---	--------------------
- 2.6% (3) An agreement or other arrangement with FDA to share results of BSE inspections performed by state inspectors with FDA

Number of BSE inspections done under agreement or other arrangement:	Total: ~200
--	--------------------
- 21.0% (4) Other BSE inspections performed by state inspectors with results reported to FDA

Number of BSE inspections done by state and results reported to FDA:	Total: ~500
--	--------------------

15. Did your state perform any BSE inspections during 2003 that are not reported in your answer to Question 14? *(Please check one.)*

N = 38

- 31.6% (1) Yes →How many? **Total: ~700 (N = 10)**
- 68.42% (2) No

16. What type of arrangement(s) does your state have with FDA for 2004 and what is the projected number of inspections that will be completed under each type of arrangement? *(Remember to use your state's reporting year.)*

N = 37 **For 2004:** *(Please check all that apply and fill in number of inspections where checked.)*

- 94.6% (1) A contract with FDA to perform BSE inspections and report results to FDA

Number of BSE inspections done under contract:	Total: ~3200 (N = 32)
--	------------------------------
- 5.4% (2) A partnership or cooperative agreement with FDA to perform BSE inspections and report results to FDA

Number of BSE inspections done under contract or partnership:	Total: ~ 400 (N = 2)
---	-----------------------------
- 2.7% (3) An agreement or other arrangement with FDA to share results of BSE inspections performed by state inspectors with FDA

Number of BSE inspections done under agreement or other arrangement:	Total: ~200 (N = 1)
--	----------------------------
- 21.6% (4) Other BSE inspections performed by state inspectors with results reported to FDA

Number of BSE inspections done by state and results reported to FDA:	Total: ~ 600 (N = 6)
--	-----------------------------

17. Did your state perform any BSE inspections during 2004, or do you expect to perform inspections, that are not reported in your answer to Question 16? *(Please check one.)*

N = 37

- 32.4% (1) Yes →How many? **Total: ~900 (N = 9)**
- 67.6% (2) No

**Appendix IV
Survey of State Agencies**

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18. For each of the firm types listed below, please indicate whether or not: (a) your state is authorized to inspect that type of firm, (b) your state conducts routine BSE inspections of that firm type, (c) your state requires registration or licensing of that firm type, and (d) your state has identified all possible firms of that type. (For each firm type, please check yes or no for each question.)

N		A. Is your state authorized to inspect this firm type?		B. Does your state conduct routine BSE inspections of this firm type?		C. Does your state require registration or licensing for this type of firm?		D. To the best of your knowledge, have you or FDA identified all possible firms of this type?	
		Yes	No	Yes	No	Yes	No	Yes	No
35	1	31	4	26	9	27	8	34	1
		88.6%	11.1%	74.3%	25.7%	77.1%	22.9%	97.1%	2.9%
37	2	36	1	29	8	32	5	37	0
		97.3%	2.7%	78.4%	21.6%	86.5%	13.5%	100%	0.0%
38	3	37	1	35	3	34	4	38	0
		97.4%	2.6%	92.1%	7.9%	89.5%	10.5%	100%	0.0%
34	4	32	2	24	10	28	6	31	3
		94.1%	5.9%	70.6%	29.4%	82.3%	17.6%	91.2%	8.8%
36	5	15	21	9	27	1	35	6	30
		41.7%	58.3%	25.0%	75.0%	2.8%	97.2%	16.7%	83.3%
36	6	16	20	10	26	1	35	6	30
		44.4%	55.6%	27.8%	72.2%	2.8%	97.2%	16.7%	83.3%
36	7	16	20	10	26	1	35	7	29
		44.4%	55.6%	27.8%	72.2%	2.8%	97.2%	19.4%	80.6%
36	8	35	1	27	9	29	7	33	3
		97.2%	2.8%	75.0%	25.0%	80.6%	19.4%	91.7%	8.3%
37	9	33	4	22	15	20	17	21	16
		89.2%	10.8%	59.5%	40.5%	54.1%	45.9%	56.8%	43.2%
37	10	36	1	27	10	14	23	32	5
		97.3%	2.7%	73.0%	27.0%	37.8%	62.2%	86.5%	13.5%
37	11	36	1	21	16	9	28	26	11
		97.3%	2.7%	56.8%	43.2%	24.3%	75.7%	70.3%	29.7%
37	12	27	10	11	26	3	34	9	28
		73.0%	27.0%	29.7%	70.3%	8.1%	91.9%	24.3%	75.7%

¹ Four states reported that there are no renderers in their state.

² Two states reported that there are no protein blenders in their state.

³ One state reported that there are no pet food manufacturers in their state.

⁴ Three states reported that there are no animal food or pet food salvagers in their state.

**Appendix IV
Survey of State Agencies**

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19. What documentation does your state complete for each BSE inspection it performs under your state's authority? (Please check all that apply.)

N = 36

- 30**
83.3% (1) FDA's BSE Checklist
- 4**
11.1% (2) BSE Checklist developed by your state
- 12**
33.3% (3) Form FDA 481- Computer generated Cover Sheet
- 10**
27.8% (4) Form FDA 483 – Inspectional Observations
- 12**
33.3% (5) Other inspection forms from your state
- 11**
30.6% (6) Other (Please specify.)

20. What documentation do you submit to FDA as part of BSE inspections that are done under your state's authority? (Please check all that apply.)

N = 33

- 26**
78.8% (1) FDA's BSE Checklist
- 2**
6.1% (2) BSE Checklist developed by your state
- 9**
27.3% (3) Form FDA 481- Computer Generated Cover Sheet
- 8**
24.2% (4) Form FDA 483 – Inspectional Observations
- 8**
24.2% (5) Other inspection forms from your state
- 12**
36.4% (6) Other (Please specify.)

21. Under your state's authority, does your state make compliance decisions associated with BSE inspections? (Please check one.)

N = 38

- 28**
73.7% (1) Yes
- 10**
26.3% (2) No → Skip to Question 23.

22. Who, in your state organization routinely makes the final inspection decision as to whether a firm is in compliance with your state's regulations? (Please enter position title(s) in box. Do not enter names.)

N = 28

27 (96.4%) of the respondents provided an answer.

23. Under your state's authority which, if any, of the following enforcement actions can you take against a firm not in compliance with your state's laws or regulations? (Please check all that apply.)

N = 38

- 34**
89.5% (1) Warning letter
- 34**
89.5% (2) Stop sale of product
- 33**
86.8% (3) Product seizure or confiscation
- 26**
68.4% (4) Injunction
- 21**
55.3% (5) Recall of product
- 27**
71.0% (6) Criminal or civil prosecution
- 12**
31.6% (7) Other (Please specify)

24. How frequently does your state report to FDA information about BSE enforcement actions taken under your state's authority? (Please check one.)

N = 37

- 25**
67.6% (1) Always → Skip to Question 26.
- 5**
13.5% (2) Almost always
- 2**
5.4% (3) Sometimes
- 1**
2.7% (4) Occasionally
- 4**
10.8% (5) Never

**Appendix IV
Survey of State Agencies**

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25. Please describe (a) the conditions or circumstances, including type of inspection and (b) the type of violations for BSE enforcement actions not usually reported to FDA. (Please use the space below, or, if you prefer, attach a separate sheet with your answer.)

N = 12

9 (75.0%) of the respondents provided an answer.

4 states responded that minor technical violations would not be reported to FDA.

4 states responded that violations found under state authority would not be reported to FDA.

26. For each of the firm types listed below, what is the level of compliance in your state with the BSE feed ban? (Please check one in each row.)

N	Type of Firm		Very High	High	Moderate	Low	Very Low	Uncertain
30	1	Renderer ¹	22	4	0	0	0	4
			73.3%	13.3%	0.0%	0.0%	0.0%	13.3%
37	2	FDA-licensed feed mills for commercial feed	29	4	0	0	0	4
			78.4%	10.8%	0.0%	0.0%	0.0%	10.8%
37	3	Non-FDA licensed feed mills for commercial feed	26	10	0	0	1	0
			70.3%	27.0%	0.0%	0.0%	2.7%	0.0%
32	4	Protein blender ²	23	5	0	0	0	4
			71.9%	15.6%	0.0%	0.0%	0.0%	12.5%
35	5	Farmers/ranchers who raise ruminants and non-ruminant animals	11	3	0	0	0	21
			31.4%	8.6%	0.0%	0.0%	0.0%	60.0%
35	6	Farmers/ranchers who raise only ruminants	11	3	0	0	0	21
			31.4%	8.6%	0.0%	0.0%	0.0%	60.0%
34	7	On-farm mixer (on-farm use only)	10	3	0	0	0	21
			29.4%	8.8%	0.0%	0.0%	0.0%	61.8%
35	8	Pet food manufacturer ³	24	7	1	1	0	2
			68.6%	20.0%	2.9%	2.9%	0.0%	5.7%
32	9	Animal food or pet food salvager ⁴	11	9	3	1	0	8
			34.4%	28.1%	9.4%	3.1%	0.0%	25.0%
36	10	Distributor of commercial feed	19	10	3	1	0	3
			52.8%	27.8%	8.3%	2.8%	0.0%	8.3%
36	11	Retailer of commercial feed	15	12	2	1	0	6
			41.7%	33.3%	5.6%	2.8%	0.0%	16.7%
35	12	Transporter/Hauler of commercial feed	7	3	1	0	0	24
			20.0%	8.6%	2.9%	0.0%	0.0%	68.6%

¹ Four states reported that there are no renderers in their state.

² Two states reported that there are no protein blenders in their state.

³ One state reported that there are no pet food manufacturers in their state.

⁴ Three states reported that there are no animal food or pet food salvagers in their state.

Section III: Testing of Animal Feed Ingredients

27. Do you take samples of animal feed to test for prohibited materials as part of BSE inspections that are done under your

N = 38
 18
 47.4% (1) Yes
 20
 52.6% (2) No → **Skip to question 33.**
state's authority? (Please check one.)

28. When did you start collecting animal feed samples to test for prohibited materials? (Please enter month and year below.)

Dates ranged from September, 1997 to June, 2004. 18 states reported dates.
 Month: _____
 Year: _____

29. How many samples did you collect and test in 2003 (as part of a BSE inspection done under your state's authority)? (Please enter number in box.)

Total: -1500
N = 17

30. How many samples do you plan to collect and test in 2004? (Please enter number in box.)

Total: -2300
N = 15

31. What type(s) of test(s) did you use? (Please check all that apply.)

N = 18
 7
 38.9% (1) Feed microscopy
 4
 22.2% (2) PCR (polymerase chain reaction)
 6
 33.3% (3) Elisa (enzyme-linked immunosorbent assay)
 7
 38.9% (4) Other (Please specify.) _____

32. Do you routinely share the results of these tests with FDA? (Please check one.)

N = 18
 11
 61.1% (1) Yes
 7
 38.9% (2) No

33. Does FDA direct your state to take samples of animal feed to test for prohibited materials as part of BSE inspections that are done for FDA? (Please check one.)

N = 38
 3
 7.9% (1) Yes
 35
 92.1% (2) No → **Skip to question 37.**

34. How many samples did you collect and test in 2003 (as part of a BSE inspection done for FDA)? (Please enter number in box.)

Total: ~100
N = 3.

35. How many samples did you collect and test in 2004 (as part of a BSE inspection done for FDA)? (Please enter number in box.)

Total: ~100
N = 2

36. What type(s) of test(s) did you use? (Please check all that apply.)

N = 2
 0
 0.0% (1) Feed microscopy
 0
 0.0% (2) PCR (polymerase chain reaction)
 1
 50.0% (3) Elisa (enzyme-linked immunosorbent assay)
 1
 50.0% (4) Other (Please specify.) _____

**Section IV: FDA Training and
Guidance for BSE Inspection and
Enforcement**

37. Does FDA provide sufficient training on BSE inspection and enforcement? *(Please check one.)*

N = 38

- 18 (1) Definitely yes
47.4%
- 12 (2) Probably yes
31.6%
- 3 (3) Uncertain
7.9%
- 5 (4) Probably no
13.2%
- 0 (5) Definitely no
0.0%
- 0 (6) No basis to judge
0.0%

38. When your state inspectors or supervisors have technical questions on performing inspections, are they answered by FDA in a timely manner? *(Please check one.)*

N = 38

- 30 (1) Always or almost always
78.9%
- 5 (2) More than half of the time
13.2%
- 2 (3) About half of the time
5.3%
- 1 (4) Less than half of the time
2.6%
- 0 (5) Never or almost never
0.0%
- 0 (6) No basis to judge
0.0%

39. How satisfactory are the answers that FDA provides to your state inspectors' or supervisors' technical questions on performing inspections? *(Please check one.)*

N = 38

- 27 (1) Very satisfactory
71.0%
- 11 (2) Somewhat satisfactory
28.9%
- 0 (3) Uncertain
0.0%
- 0 (4) Somewhat unsatisfactory
0.0%
- 0 (5) Very unsatisfactory
0.0%
- 0 (6) No basis to judge
0.0%

40. When your state inspectors or supervisors have questions on potential violations and enforcement actions are they answered by FDA in a timely manner? *(Please check one.)*

N = 38

- 28 (1) Always or almost always
73.7%
- 8 (2) More than half of the time
21.0%
- 1 (3) About half of the time
2.6%
- 0 (4) Less than half of the time
0.0%
- 0 (5) Never or almost never
0.0%
- 1 (6) No basis to judge
2.6%

41. How satisfactory are the answers that FDA provides to your state inspectors' or supervisors' questions about potential violations and enforcement actions provided by FDA? *(Please check one.)*

N = 38

- 21 (1) Very satisfactory
55.3%
- 12 (2) Somewhat satisfactory
31.6%
- 2 (3) Uncertain
5.3%
- 2 (4) Somewhat unsatisfactory
5.3%
- 0 (5) Very unsatisfactory
0.0%
- 1 (6) No basis to judge
2.6%

Section V: Comments

(For the following questions, please use the space here to provide your answers, or, if you prefer, attach a separate sheet with your answer.)

42. In your opinion, what areas of FDA's BSE inspection program seem to be working well and what areas need to be improved?

N = 38

29 (76.3%) of the respondents provided comments.

18 states responded that the BSE inspection program is working well, especially for inspections of renderers, protein blenders, and feed mills.

7 states responded that FDA needs to place more emphasis on farm mixers and feeding operations.

4 states responded that FDA needs to place more emphasis on transportation of animal feed.

6 states responded that FDA needs to share inspection results and enforcement actions with state agencies.

2 states responded that FDA needs to be more decisive in taking enforcement action, when warranted.

43. No questionnaire of this type can cover all aspects of a topic. If you have further concerns or comments concerning FDA's BSE inspection program, please comment below. Or, if you prefer, mail or email your comments to us separately.

N = 38

13 (34.2%) of the respondents provided comments, however 1 did not attach comments to questionnaire, resulting in only 12 responses (31.6%).

Appendix IV
Survey of State Agencies

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**Food and Drug Administration BSE Inspection Program: Survey of States with
Contracts and Other Agreements with FDA**

Please complete for all individuals providing information for this questionnaire.

Name: _____

Title: _____

Department: _____

Mailing Address: _____

Phone Number: _____ Email: _____

Name: _____

Title: _____

Department: _____

Mailing Address: _____

Phone Number: _____ Email: _____

Name: _____

Title: _____

Department: _____

Mailing Address: _____

Phone Number: _____ Email: _____

Please attach additional sheets if needed.

Thank You!

Chronology of FDA's Feed Ban and Proposed Rulemakings

August 4, 1997

FDA feed ban took effect, prohibiting certain materials in ruminant feed to prevent the establishment and spread of BSE if it were to appear in U.S. cattle herds. FDA took this action because it had been an industry practice to feed proteins to ruminant animals that could transmit the infective agent that causes BSE. Additionally, research in the United Kingdom suggested that variant Creutzfeldt-Jacob Disease (vCJD) in humans is linked to eating cattle infected with BSE. The feed ban requires that firms, with some exceptions, take the following actions:

- label feed and feed ingredients that contain most proteins from mammals (prohibited material) with a cautionary statement “Do not feed to cattle or other ruminants,”
- have procedures to protect against commingling or cross-contamination if they handle both prohibited and nonprohibited feed and feed ingredients by using either equipment dedicated exclusively to feed or ingredients intended for cattle or using cleanout procedures or other adequate means to prevent carryover, and
- maintain records so that feed and feed ingredients that contain or may contain prohibited material can be tracked from receipt through disposition.

According to FDA's rules, firms that transport both types of materials must also follow these procedures. Additionally, prohibited materials may be used in pet food and in feed for poultry, swine, horses, and other nonruminant animals. Lastly, FDA designated a number of cattle- and other animal-derived items as exempt from the ban—and hence, allowable in cattle feed. These items include blood and blood products, plate waste, gelatin, milk and milk protein, and any product whose only mammalian protein consists entirely of protein from pigs and horses. FDA has also not regulated the use of poultry litter in feed.

October 30, 2001

FDA held a public hearing to solicit information and views regarding ways in which the current feed ban and its enforcement might be improved or to determine if any new objectives should be considered. FDA took this action because BSE had spread beyond the United Kingdom to most countries in western and central Europe and Japan. FDA asked for responses to 17 questions, including the following:

- Should FDA require dedicated facilities for the production of animal feed containing mammalian protein?
- Should FDA require dedicated transportation of animal feed containing mammalian protein?
- Should FDA license renderers and other firms engaged in the production of animal feed containing mammalian proteins?
- Should FDA revoke or change any of the current exemptions in the current rule?
- Should FDA require pet food to contain the cautionary statement?
- Should FDA extend the recordkeeping requirement beyond 1 year?
- Should FDA request authority to assess civil monetary penalties?

November 6, 2002

FDA published an advanced notice of proposed rulemaking announcing that it was considering revising the feed ban and asking the public to comment on certain possible modifications. FDA explained that shortly after its October 2001 public hearing, USDA released a report by the Harvard Center for Risk Analysis on the findings of a major, 3-year initiative to develop a risk assessment model and assess the risk of BSE in the United States. The model concluded that the risk to U.S. cattle and to consumers from BSE is very low, but certain new control measures could reduce that small risk even further. Therefore, based on comments received at the public hearing and the findings of the Harvard Study, FDA asked for public comment on various ways that the BSE feed ban could be strengthened, including the following questions:

- Should tissues that are known to be at higher risk for harboring the infective agent for BSE, such as brain and spinal cord from ruminants 2 years of age or older be excluded from all rendered products?
- How extensive is the use of poultry litter in cattle feed, what is the level of feed spillage in poultry litter, and what would be the impacts resulting from banning poultry litter in ruminant feed?
- Should pet food for retail sale carry the cautionary statement “Do not feed to cattle or other ruminants?”

-
- Are there practical ways, other than dedicated facilities, for firms to demonstrate that the level of carryover of prohibited material in a feed mill could not transmit BSE to cattle or other ruminants? If so, what is the safe level of carryover of prohibited material and what is the scientific rationale for establishing this safe level?
 - To what extent is plate waste used in ruminant feed and what would be the impacts from excluding this material from ruminant feed?

January 26, 2004

FDA announced that it would be issuing interim final rules to strengthen existing BSE firewalls, including banning a wide range of cattle material from human food, dietary supplements, and cosmetics, and strengthening the 1997 feed ban through an extended list of banned feeding and manufacturing practices.

July 14, 2004

FDA, with USDA, announced that the agencies are considering additional measures to protect the public from the health risk associated with BSE and to prevent the spread of the disease in U.S. cattle and are asking for public comment. The agencies are considering additional safeguards based on the recommendations of a panel of international experts convened by the Secretary of Agriculture to review the U.S. regulatory response following the finding of a BSE-positive cow in Washington State in December 2003. In addition to some of the measures FDA had planned to take in an interim final rule, the international panel recommended broader measures, such as banning all mammalian and poultry protein from ruminant feed. Since these recommendations would require significant changes in current feed manufacturing practices and could make some previously announced proposals unnecessary, FDA requested additional information and public comment on the panel recommendations and other measures, including the following:

- What information is available to support or refute the assertion that removing tissues that are known to be at higher risk for harboring the BSE infective agent, such as brain and spinal cord tissue, from all animal feed is necessary to effectively reduce the risks of cross-contamination of ruminant feed or of misfeeding on the farm?
- If FDA prohibits high-risk tissues from all animal feed, would there be a need to require dedicated facilities, equipment, storage, and transportation?

- What information is available to support banning all mammalian and poultry meat and bone meal from ruminant feed?
- If FDA prohibits high-risk tissues from all animal feed, what information is available to support banning all mammalian and poultry meat and bone meal from ruminant feed?
- Can high-risk tissues be effectively removed from dead stock and nonambulatory cattle so that the remaining material can be used in animal feed, or is it necessary to prohibit the entire carcass from use in all animal feed?
- Do FDA's existing authorities under the Federal Food, Drug, and Cosmetic Act and under the Public Health Service Act provide a legal basis to ban the use of high-risk cattle tissues and other cattle material in nonruminant animal feed, given that such materials have not been shown to pose a direct risk to these animals?

FDA also issued an interim final rule on July 14, 2004, to prohibit certain cattle materials in FDA-regulated food, including dietary supplements, and cosmetics, to minimize potential human exposure to the BSE infective agent. Specifically, FDA prohibited use of the brain, skull, spinal cord, and other specified tissues of cattle that are 30 months or older; small intestine and tonsils of all cattle; material from nonambulatory disabled cattle or cattle not inspected and passed for human consumption; and beef that is mechanically separated from bones. FDA took this action in response to the finding of a BSE-positive cow in Washington State in December 2003 and to conform with an interim final rule issued by USDA in January 2004 declaring these materials unfit for human consumption.

Comments from the Food and Drug Administration

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

January 13, 2005

Robert A. Robinson
Managing Director, Natural Resources and Environment
Natural Resources and Environment Team
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Robinson:

Please find the enclosed comments from the Food and Drug Administration on the GAO draft report entitled, *MAD COW DISEASE, FDA's Management of the Feed Ban Has Improved But Oversight Weaknesses Continue to Limit Program Effectiveness, GAO-05-101*. The agency provided technical comments directly to your staff.

We appreciate the opportunity to review and comment on this draft report before its publication as well as the opportunity to work with your staff in developing this report.

Sincerely,

A handwritten signature in black ink, appearing to read "Lester M. Crawford".

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

Enclosure

Appendix VI
Comments from the Food and Drug
Administration

General Comments by the Department of Health and Human Services' Food and Drug Administration on the Government Accountability Office's Draft Report, MAD COW DISEASE: FDA's Management of the Feed Ban Has Improved But Oversight Weaknesses Continue to Limit Program Effectiveness, (GAO-05-101)

The Food and Drug Administration (FDA) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report. While GAO has raised a few areas to further strengthen the feed ban program, FDA does not believe that material weaknesses were identified that support GAO's position that "various oversight weaknesses continue to limit program effectiveness of the ban and place U.S. cattle at risk of spreading BSE."

FDA commends GAO for conducting such a thorough and diligent study on such an important program and we appreciate the recognition of the enhancements put into place as we have expanded our activities. We note that this work was conducted in October 2003 through November 2004, and involved visits to 17 of 19 FDA district offices, visits to many states conducting inspections under the ruminant feed ban, a significant review of our data systems and multiple meetings with headquarters personnel. A considerable amount of FDA resource time has been devoted to responding to the information requests of this GAO study. While FDA has endeavored to provide both timely and complete responses, we note that FDA field offices alone expended approximately 1500 hours nationwide to provide the 413 inspection reports and to respond to questions from GAO during their visits. This does not include the ongoing information collection requested by GAO after the exit conference, of follow-up information on approximately two hundred feed samples.

FDA's ruminant feed ban regulation, our implementation of which uses a risk-based approach, potentially involves a wide variety of firms involved in the animal feed industry. Every firm that manufactures, transports, distributes or sells animal feed or feed ingredients for any animal species is subject to inspection under the FDA ruminant feed ban compliance program, regardless of whether prohibited material is utilized. Even swine and poultry farms that mix their own feed and grocery stores that sell pet food are potentially subject to inspection under this rule. All operations feeding ruminants, such as dairy and beef cattle, are also subject to the rule. In consideration of the limited resources for inspecting this large population of firms, FDA is obligated to set priorities for inspecting a meaningful subpopulation of these regulated firms.

FDA provides inspection priority direction to FDA and state investigators through publication of an inspection priority document as part of the BSE/Ruminant Feed Inspection Compliance Program guidance document. The highest priority for inspection is directed towards firms that are manufacturing or processing animal feeds or feed ingredients that contain prohibited material. This industry segment, which includes renderers, protein blenders, and feed mills, represents the most important industry segment to ensure that ruminant feeds do not contain prohibited material. This industry group is inspected on an annual basis.

Generally, firms outside of these segments collectively have a lower priority for inspection since the operations of the firms in the high priority segment of the industry pose the greatest risk of resulting in contaminated feed. Other segments, such as cattle feeders, are of interest to the FDA, but there are estimated to be over one million ruminant feeders in the U.S. While FDA does not have the resources to fully inspect certain industry segments, the agency continues to develop and utilize educational tools to complement inspections and to promote voluntary compliance in these large industry segments. FDA will additionally implement inspectional initiatives to increase its presence in some of these less inspected segments, such as

See comment 1.

transporters and animal feed salvagers, based on our assessment of compliance and risk in these industry sectors.

We also do not agree with the assertion by GAO concerning the format with which FDA summarizes ruminant feed ban reporting of inspection results. FDA has provided a degree of transparency related to these inspections that is unprecedented, compared to any other inspection program. All data related to BSE inspections are posted on an Internet site that is available to Congress, industry and the public. FDA took this action because of the visibility of this inspection program and because of the recognition that one of the best tools to obtain compliance with the feed ban was public disclosure of our findings. While GAO may disagree with the context provided by any summary documents, our web site allows the user to analyze the data, in a multitude of ways, to provide their own contextual reference.

RECOMMENDATIONS FOR EXECUTIVE ACTION

To further strengthen oversight and enforcement of the animal feed ban and to better protect U.S. cattle and American consumers, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following 9 actions:

1) Develop uniform procedures for identifying all firms subject to the feed ban.

FDA Comment

FDA has already identified the merits of using a consistent procedure for identifying additional firms subject to its jurisdiction and has revised the Investigational Operations Manual (IOM).

As noted in the report, FDA acknowledges that more firms are subject to the feed ban than the over 14,800 that have been inspected to date. However, FDA's current inspectional strategy has been to focus on renderers, protein blenders, and feed mills, which we believe are the primary means of controlling feed and feed ingredients that may contain prohibited material. FDA believes that it has uniform procedures for identifying and inspecting these higher risk firms and that we have been successful in covering this inventory. The survey data collected by GAO from the states supports that, to a great extent, this inventory of firms has been both identified and inspected.

The issue that GAO raises in the draft report is related only to the lower risk firms that are purchasing feed ingredients from one of the higher risk establishments. FDA does not have the resources to inspect all ruminant feeders, transporters/haulers of feed, feed retailers and feed distributors that may be subject to this regulation. This total inventory is massive and for most of these firms there is either no commercial handling of prohibited material since they are handling only packaged product (like pet food), or there is limited manipulation of the product that would allow for contamination. Therefore, the FDA approach has been to selectively inspect sample firms in this lower risk category to assess their level of compliance with the regulations, and to assist in determining additional educational efforts that may be needed. FDA has inspected all firm types in these lower risk industry segments and continues to expand the number of inspections conducted both by FDA and the states in these lower risk categories. When FDA identifies a specific segment that may need additional inspectional coverage, the agency will issue specific assignments to broaden our coverage. This is the situation with the transporters/haulers and pet food salvagers for which the FDA's Center for Veterinary Medicine (CVM) is currently drafting an assignment to FDA's field operations.

See comment 2.

Appendix VI
Comments from the Food and Drug
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GAO identified a process used by some FDA investigators, on some of the observed inspections, to help FDA identify additional firms. This process entails investigators writing down the names of the suppliers and customers of firms during inspections to check against the inventory of active firms. While there is value to GAO's suggestion, the recording of the supplier and customer names and later checking them against an inventory of active firms after all inspections would take additional resource time and is not resource neutral as suggested by GAO. The current BSE inspection module is 7.5 hours. Such inventory improvement would utilize time that would have to be diverted from conducting additional inspections. Nevertheless, FDA has already identified the merits of consistently using this approach. Earlier this year, as part of FDA's ongoing improvements in our security awareness program, we recently changed our 2005 Investigations Operations Manual (IOM) regarding the standard narrative report. IOM Chapter 593.03, Individual Narrative Headings, has been revised to advise the FDA Investigator to verify, during the initial inspection, distribution patterns for the firm's products, raw materials, and components to firms which warehouse or further process products which may be subject to FDA regulations. The 2005 IOM revision also reminds FDA District Offices that any new information should be incorporated into their Official Establishment Inventory (OEI) improvement activities. Lastly, this revised section also provides a cross-reference to the necessary section of the IOM that describes how to add firms to a District OEI. Once the 2005 IOM has been finalized, ORA will alert Districts through our various mechanisms to this change, which affects all ORA Inspection programs, including the BSE Inspection Program. We will also discuss this recommendation with the Field Veterinary Committee for incorporation into the next Compliance Program Guidance revision of the BSE Inspection program.

See comment 3.

2) Require that firms that process with prohibited material notify FDA. If FDA believes it does not have legislative authority to require this, it should seek that authority from the Congress.

FDA Comment

FDA's current regulations do not require that firms handling prohibited material notify FDA and the Federal Food, Drug, and Cosmetic Act (FFDCA) does not currently require such notification. If such a notification program were implemented, FDA would need significant additional resources to develop the notification regulation, develop collection and monitoring tools, collect the information, monitor the information and compliance with the requirement, and conduct follow-ups. FDA believes that our current approach of working collaboratively with our state counterparts does give us a good opportunity to keep abreast of changes firms may make in the use of prohibited material and to use our resources to focus on high risk firms. We continue to enhance our working relationships with our state counterparts to facilitate the exchange of such information.

In support of identifying all firms of higher risk, FDA has already initiated the process of reviewing records for food facilities that have registered with FDA under section 415 of the FFDCA, and determining whether there are any facilities that may potentially handle prohibited material that have registered but that we have not previously inspected. Under section 415 of the FFDCA, facilities that manufacture, process, pack, or hold food for consumption in the United States must register with FDA. When the facility registers, it must indicate if it manufactures, processes, or packs certain categories of food. The facility may voluntarily indicate if it manufactures, processes, or packs other categories of food. All categories of animal food are among those that facilities may voluntarily report to FDA. While the registration system has certain limitations, including an exemption for farms that process feed for their own

See comment 4.

animals, we believe that the registration information could still lead us to identify additional facilities that handle prohibited material.

3) Develop guidance for inspectors to systematically use feed microscopy and/or polymerase chain reaction (PCR) to verify the safety of cattle feed and to confirm the adequacy of firms' procedures for ridding equipment and vehicles of prohibited material before they are used for cattle feed or feed ingredients.

FDA Comment

Since no test currently exists for the detection of the infectious prion agent that causes BSE in feed, analysis of feed is not by itself a means of verifying the safety of cattle feed. Additionally, feed microscopy and/or PCR are not adequate methods to make compliance decisions based on test results alone about the presence of prohibited material with respect to the ruminant feed ban rule. The feed microscopy method has limitations and the rule has exemptions. Feed microscopy generally can only detect the presence of mammalian tissue, through the identification of either bone or hair. In certain situations, feed microscopy can only detect the presence of animal tissue when blood is detected. The present ruminant feed ban allows for certain exemptions to the mammalian protein prohibition. Exempted materials include pure porcine meat and bone meal, blood (from any animal species, including ruminants), gelatin, and milk protein. Further, there is no prohibition on the use of non-mammalian proteins (e.g., poultry meal). The detection of certain non-specific materials, such as bone or muscle, may be the result of exempt ingredients, such as ruminant blood meal, pure porcine meat and bone meal, or poultry meal. PCR has similar limitations since the test cannot differentiate between prohibited material ingredients and certain ruminant-containing exempt ingredients, such as ruminant blood, ruminant milk products, and plate waste. Since feed microscopy and PCR cannot differentiate prohibited material from other acceptable materials, the analytical results cannot be used to verify the presence [or absence] of prohibited material, nor used for confirming the adequacy of clean-out measures.

On August 18, 2003, FDA/CVM issued a sampling assignment to the FDA field staff for the collection of 600 domestic samples [increased to 900 samples for the current fiscal year]. The characteristics of the ruminant feed ban sampling assignment are unique when compared to other FDA sampling programs. Other programs are more simply based on methodology that can definitively detect the presence of the objectionable contaminant or pathogen. Further, the nature of the contaminants in some of the other programs allow for the establishment of tolerance levels. The mere detection of a pathogen or some of these contaminants, possibly with respect to an established tolerance, is sufficient to result in the finding of a violation in these other programs. In contrast to these other programs, analytical findings alone under the ruminant feed ban program cannot establish the occurrence of a violation to the rule. As the ruminant feed ban assignment notes, positive analytical findings necessitates follow-up evaluations in determining whether the findings were indeed the result of ruminant feed ban violations.

The fairly recent implementation of this unique ruminant feed ban sampling program has involved efforts to educate laboratory personnel as to the limitations of the methodology, and the approach in categorizing the lab results. Laboratory personnel have been educated through conference calls, training, and individual telephone conversations in classifying these samples. Further, field investigators have been instructed that regulatory action should not be taken on the basis of sample analysis alone. (See the Enforcement and Regulatory follow-up sections in the BSE/Ruminant Feed Ban Inspections Compliance Program Guidance and the

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See comment 5.

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Domestic Feed Sampling Assignment, respectively.) In the next fiscal year, FDA intends to provide additional guidance to describe the variety of situations where animal, mammal and/or ruminant tissue may be present in an animal feed or feed ingredients. Through an analysis of the experience derived from the first year of the sampling assignment, FDA will revise overall sampling instructions in the sampling assignment, with these sampling procedures eventually being incorporated into the BSE/Ruminant Feed Ban Inspections Compliance Program guidance document.

4) Collect feed test results from states that sample feed to help verify compliance with the feed ban.

2002 GAO BSE Study

Recommendation to track enforcement actions taken by states.

2002 FDA Comment

FDA thanks the GAO for this recommendation. FDA needs to more fully evaluate the impact of this recommendation. FDA does not have the authority to require that all states track and report to FDA enforcement actions taken. Currently, state laws differ on what inspection and enforcement authorities each state has and the ability of each state to provide such information to FDA. We do strongly support the concept of voluntarily sharing inspection and enforcement actions taken by FDA and our state partners. This was one of the primary motivators for our quarterly FDA-State regulator BSE meetings to provide a forum to share such potentially confidential information.

2004 GAO BSE Study

Recommendation to collect feed test results from states that sample feed to help verify compliance with the feed ban.

FDA Comment

We have included the comment from GAO's 2002 recommendation on tracking enforcement actions by states as these two recommendations present some of the same difficulties for the agency. First is the fact that each state agency may enforce different state laws and regulations regarding feed manufacturers and these laws and regulations may not be the same as the federal rules. The collection of enforcement actions and sample results could, therefore, actually confuse the enforcement and compliance national picture rather than enhance it. Second, concerning both enforcement and collection of samples, until FDA and the states have developed a standard for sampling procedures, analytical techniques, and enforcement strategies, the shared data would be considered skewed and potentially misleading. While enforcement could be equalized through adoption of equivalent regulations by the states, FDA would have to evaluate each state enforcement program through our audits, which would require field inspection resources. Accepting sample results would also require not only the use of equivalent testing protocols, e.g. using acceptable ELISA test kits, but also may involve the evaluation of the laboratory and laboratory personnel. Performing this type of evaluation would require resources currently not available to FDA. With the current test and with the implementation of the very sensitive PCR test, the test could be positive for exempt ingredients or for non-ruminant material such as mice, rats, etc.

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To enhance our sampling/analytical aspects of this program, FDA is incorporating collection of samples under the Feed Manufacturing/BSE state contracts. States will submit these samples to FDA laboratories to support FDA's own efforts in surveying the animal feed industry. FDA is also considering expanding, as funding permits, the Electronic Laboratory Exchange Network (eLEXNET) to include animal feeds. eLexnet is a nationwide laboratory data network that allows member laboratories the ability to detect, compare and communicate findings. Also with proper funding, FDA will add the state contract feed manufacturer programs into eSAF (electronic state access to FACTS) in FY05/06. Once the programming is funded and completed, the states will be able to enter their contract data (or other inspections) into the system and both FDA and the state will be able to review all the entered inspections for that particular state. This will improve the timeliness of information collected by states during feed establishment inspections.

5) Develop a sample design for FDA's inspectors to use for sampling finished feed and feed ingredients that will allow FDA to more accurately generalize about compliance with the feed ban from the test results.

FDA Comment

Sampling of finished feed and feed ingredients cannot serve as a basis to generalize compliance with the feed ban. As explained in the above responses, the current tests available and in use today are not definitive for prohibited material. Feed microscopy has limitations, including that it can demonstrate animal tissue and can sometimes determine if the tissue is mammalian, but cannot distinguish between prohibited mammalian protein, non-prohibited protein, and exempt mammalian protein. The test being used today [feed microscopy] provides information that there may be a potential problem. The only way to determine compliance with the feed ban is to conduct an inspection of the firm. The feed sampling assignment is designed to be an additional way to review products in the marketplace. Finding a positive result from feed microscopy provides information for us to conduct targeted follow-up inspections but does not by itself prove the presence of prohibited material and a violation of the ruminant feed ban.

The August 18, 2003 domestic assignment directs ORA Field personnel to routinely sample and analyze feed to verify compliance with the feed ban. (See excerpt below.)

Sampling Information:

A. Sample Selection

Products should be selected for sampling using the following criteria:

1. Animal feed, feed ingredients, and other animal feed products as identified in Attachment B to this assignment.
2. Products intended for ruminant animals. These products should be given the highest priority for collection. At least one half (½) of the samples should be selected from these products if possible.
3. Animal feed, feed ingredients, and other animal feed products that are labeled as containing animal protein but do not bear the caution statement "Do not feed to cattle or other ruminants" on the label.

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4. Animal feed, feed ingredients, and other animal feed products that do not list mammalian protein in the product name or ingredient list.

5. Each sample should represent a different source, processor, or manufacturer if possible.

Attachment B

Products/ Product Codes Covered by this Assignment:

69 – Medicated Animal Feeds

69 [] [] [] [] [] All Products

70 – Non-Medicated Animal Feeds

70 [] [] [] [] [] All Products

71 – By-product for Animal Food

71 [] [] [] [] [] All Products

6) Seek authority from the Congress to require the cautionary statement on feed or feed ingredients that are intended for export and that contain prohibited material. In the meantime, FDA should encourage firms to include such cautionary statement on these exports.

FDA Comment

The Federal Food, Drug, and Cosmetic Act currently does not include a provision that directly requires feed or feed ingredients intended for export to bear the cautionary statement. We note that, if FDA determined that it would be appropriate for the agency to adopt a policy encouraging exporting firms to voluntarily include a cautionary statement on feed labels, the agency would first need to determine whether such a policy must be issued under FDA's Good Guidance Practice regulations at 21 CFR 10.115. Under those regulations, a guidance document is a document that includes the agency's "interpretation of or policy on a regulatory issue." For the most part, FDA focuses its policies on matters under its regulatory authority. In addition, before FDA could adopt a policy to encourage the use of the cautionary statement on exports, it would need to determine that such a statement would not be inconsistent with the laws of other countries in light of the requirement in section 801(e) of the Federal Food, Drug, and Cosmetic Act that the product is not in conflict with the laws of the country to which it is intended for export.

FDA has a comprehensive program that reviews the entry of all feed commodities that either are ingredients or may end up as ingredients in ruminant feed. FDA detains animal feeds or feed ingredients that contain ingredients of animal origin and that are imported from countries identified as having BSE or being at risk for having BSE. This system does not rely upon other countries to enforce FDA labeling requirements for feed with prohibited material. Other countries have similar programs to refuse entry to imported products that pose a risk of BSE. Each country thus assumes responsibility for enforcing its own laws with respect to BSE.

Even if FDA were to require products for export that contain prohibited material to include the cautionary statement, this statement might not make the product acceptable to the importing

See comment 7.

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country and may conflict with the country's own label requirements. FDA refuses import of products into the U.S. with such material from BSE risk countries regardless of whether they have such a warning because of the risk of diversion.

Currently FDA's guidance for exports, as excerpted below, focuses on clearly labeling the product for export and providing guidance on material that may be brought back into the U.S.

PRODUCTS FOR EXPORT

* Prohibited protein product destined for export should be marked "FOR EXPORT ONLY" on the shipping containers if appropriate and on documents accompanying the shipment. No other labeling would be required for purposes of this regulation but there may be additional labeling requirements for the country of destination.

* Any prohibited protein product destined for export which is diverted back to domestic commerce for any reason (salvage, quality, etc.), will be subject to all of the requirements of the regulation. This will include the requirement to label the product with the cautionary statement "Do not feed to cattle or other ruminants."

* Responsibility for these prohibited protein products rests with the owner of the goods (holder of the title to the goods). The owner is responsible for assuring that they are not diverted back to domestic commerce unless they meet the requirements of the regulation, including use of the cautionary labeling statement.

7) Ensure that procedures for alerting USDA and states are followed when inspectors discover that feed or feed ingredients with prohibited material may have been fed to cattle.

FDA Comment

FDA has and continues to coordinate closely with USDA and state officials on issues related to BSE. FDA has notified both States and USDA when the agency assessment was that their involvement was important from a public health perspective. Nevertheless, FDA accepts the GAO recommendation and will consider notifying USDA to allow full information to be exchanged with USDA whenever there has been a recall in which prohibited material from domestic or from an imported source may have been used as an ingredient in feed, or as feed for ruminants.

The GAO draft report states that "...although FDA has procedures for alerting USDA and states when it discovers that cattle may have consumed feed that contains prohibited material, FDA officials told us that they have never given such notification even though they have identified the prohibited material being used in cattle feed in the past. FDA said that notification is not needed because BSE has not been discovered in a cow born in the United States...."

The section referenced by GAO is found in the FDA compliance program guidance entitled BSE/Ruminant Feed Ban Inspections, and pertains to recalls. It provides "generic" scenarios that could be encountered by field personnel and suggests appropriate courses of action. The purpose of this information is to provide guidance to assure similar recall situations will be handled in a consistent manner, and to reduce the burden on FDA of having to re-evaluate

See comment 8.

situations that present the same variables. This compliance program guidance is not intended to cover all situations, and any new or novel scenarios will require review and evaluation by CVM. The guidance to contact USDA is found in the second scenario on "prohibited material from domestic or from an imported source is used as an ingredient in feed, or as feed to ruminants" and is cited below:

U.S. manufacturer of non-ruminant animal feeds uses prohibited material from a domestic source, or from an imported source, and that feed is fed to ruminants either as a supplement (i.e., dairy cow supplement), by mistake, or unknowingly due to inadequate flushing/cleaning of equipment.

(1) **Classification:** Class II

(2) **Reason:** The ruminant feed or feed ingredient contains prohibited material, with or without a caution statement.

(3) **Action:**

- **Production/Distribution:** Pending results of the investigation.
- **Publicity:** Press should be issued immediately by the responsible firm and/or FDA in accordance with established policy for Class I recalls. Publication in the FDA Enforcement Report once the recall action has been classified.
- **Recall:** Pursue voluntary recall to the retail level by the responsible firm, or seek FDA requested recall.
 - **Depth:** Retail level
 - **Notification:** 100%
 - **Effectiveness Checks:** Level A, 100% verification of notification and appropriate response
 - **Audit Checks:** Level B (25%) to direct consignees (distributors/retailers). Level B (25%) to retail accounts of audited distributors
 - **Inspection:** GMP inspection is indicated to review production controls, scope of possible adulteration, extent of time such practices have been ongoing, and to obtain necessary recall information
 - **State Involvement:** Advise State counterparts of the situation and enlist their assistance in monitoring.
 - **Animal Control:** Assess control over the disposition of ruminant animals fed the prohibited protein so as to prevent their slaughter for human food or other animal feed. Coordination with States and USDA/FSIS should be considered. Consult with CVM regarding coordination and regulatory approach of animal disposition.
 - **Disposition of recalled /held product:** Oversee appropriate disposition of feed and status of animals that have been fed the feed. Determine if relabeling feed with the warning label is an option

FDA believes that it has followed this guidance and considered notification of USDA. While it is true that FDA has not notified USDA of every incident when animal feed was recalled and potentially fed to ruminants, FDA does consider the need to notify USDA based on our assessment of the facts in each unique situation. In each case FDA looks into the source of the prohibited material (imported or domestic source), what species of ruminant is it being fed to

(cattle or other species not known to acquire natural infection by the agent of BSE), the potential level of contamination with prohibited material in the feed, as well as the level of evidence available to determine if ruminant animals may have actually consumed any prohibited material.

Again, FDA will continue to coordinate closely with USDA and state officials on all issues related to BSE.

8) Modify the BSE inspection form to include questions inspectors can use to document whether firms that process or handle cattle feed or feed ingredients have procedures to ensure the cleanliness of vehicles they use to transport that cattle feed and feed ingredients.

FDA Comment

FDA has attempted to limit the number of changes to avoid having multiple versions of the reporting tool in use as well as to enhance the quality of the data. However, we will consider whether modifying the reporting tool would be appropriate. We would emphasize that the checklist is an inspection reporting tool, not the guidance for the inspection. As a reporting tool, it reflects the overall results of the inspection but does not capture every item that is inspected, reviewed, or evaluated during the inspection. The Compliance Program provides comprehensive instructions to the inspectors about inspection methods, areas to look at, records to review, and questions to ask. The following are two excerpts from the Compliance Program which specifically include review of transport conveyances:

Firms Avoiding Commingling with Adequate Clean-out Procedures - If the same equipment is shared for *both* products containing prohibited material *and* products containing only non-prohibited material, describe the clean-out procedures. Clean-out can consist of physical cleaning (e.g. vacuuming, sweeping, washing), flushing, sequencing, or other means, either alone or in combination with separation measures, that are adequate to prevent carryover of prohibited material into runs that are intended to be free of prohibited material. Clean-out procedures should be used on all equipment and conveyances (e.g. trucks, rail cars) that handle both prohibited material and non-prohibited material.

Feed Storage. [This section is included in the information on inspection of ruminant feeders]

Feed storage, particularly in operations where both ruminant and non-ruminant species are being fed, should be examined. If ruminant feeds and non-ruminant feeds are stored in the same location, the investigator should note the procedures used for ensuring that ruminant animals are not fed non-ruminant feeds and should take photographs or draw diagrams of feed bins and equipment. In particular, investigators should note whether:

- Feed bins are labeled to identify ruminant and non-ruminant feed. (This is not required by 21 CFR §589.2000 but will help the investigator determine whether ruminants have been fed non-ruminant feed.)
- Bulk feeds for ruminants are separated from non-ruminant feeds for preventing mix-up, commingling and/or cross-contamination (This is not required by 21 CFR §589.2000 but will help the investigator determine whether ruminants have been fed non-ruminant feed.)
- Transportation and feed equipment handling both ruminant and non-ruminant feeds is either separate or adequately cleaned (See Section (2)(c)).

See comment 9.

9) Ensure that inspection results are reported in a complete and accurate context.

FDA Comment

FDA believes that it has reported inspection results in a complete and accurate context.

GAO states that FDA has reported that industry is 99 percent in compliance with the feed ban. GAO further states that they do not believe that FDA has enough information or enough current information to cite a rate of compliance. GAO also notes that FDA has not inspected the universe of firms subject to the ban, many inspections are five or more years old, and inspections are largely paperwork review with very little testing to confirm compliance.

We do not agree with GAO's conclusion that FDA is reporting data that is incomplete and not accurate. FDA has made tremendous efforts, and at great cost, to have every inspection posted on FDA's Internet site. This extraordinary level of transparency, which is unique to this program, allows Congress, Industry and the public to view the inspection results, virtually at the same time as it is entered into the agency's FACTS system. The data is available to be searched and sorted by any number of variables to allow the user to ascertain their own perspective on the data. Additionally, FDA publishes CVM Updates on "Ruminant Feed (BSE) Enforcement Activities." These updates have been published on a periodic basis since January 10, 2001. These reports identify inspection results by type of industry using the standard FDA inspection classification criteria. At FDA's exit conference with GAO, GAO advised that these updates were an accurate and complete depiction of BSE inspection results.

While we understand GAO's perception with regard to the one line synopsis of overall inspection results as having a confusing message, this confusion is not due to a lack of candor on the part of the agency. We also do not agree that our "inspections are largely paperwork review with very little testing to confirm compliance." Our BSE inspections are thorough assessments where the inspector spends a considerable amount of their inspection time on the plant floor judging the firm's compliance with the feed ban regulation. Furthermore, review of paperwork, including records of feed ingredient receipt and lists of feed ingredients, are one component of our inspections and are crucial to FDA enforcement of the feed ban. FDA believes that its current regulatory approach, of assuring compliance of FDA's feed rule by the major suppliers and users of cattle feed, is the most effective approach in making sure the public health is protected.

See comment 10.

The following are GAO's comments on the Food and Drug Administration's letter dated January 13, 2005.

GAO Comments

1. We believe the report identifies numerous oversight weaknesses that continue to limit program effectiveness and place cattle at risk. The purpose of the feed ban firewall is to prevent the exposure and spread of BSE. A well enforced feed ban is even more critical now that BSE has been discovered in cattle in North America. As shown in our report, FDA does not know the compliance status or risks posed by firms it has not identified, inspected or reinspected for many years. FDA acknowledged that many more firms are subject to the feed ban than have been inspected to date but said the agency must set priorities for the number and types of firms it can identify and inspect with limited inspection resources. We agree with FDA's use of a risk-based inspection approach; however, FDA acknowledges the need to increase inspections of certain industry segments, such as transporters and animal feed salvagers. Moreover, for firms that FDA inspects, it does not routinely sample feed to verify whether the operating procedures observed by its inspectors are actually preventing prohibited materials from contaminating cattle feed. Our recommendations are aimed at ensuring that FDA has a strategy for maximizing the effectiveness of its limited inspection resources, targeting inspections, and using feed tests to minimize the risk of cattle being fed prohibited material.
2. Our concern is precisely that the data are being analyzed and interpreted in an erroneous context. Specifically, when FDA and industry used those data to assert a 99 percent compliance rate with the feed ban, they took that information out of context. While industry compliance may in fact be quite high for firms FDA has inspected recently, FDA's data are not sufficient to project compliance industrywide. FDA does not know the status of compliance for firms that have never been inspected or have not been reinspected in years. In addition, compliance history is lost—firms that had serious and long-standing violations are classified as “in-compliance” once FDA determines that the problems are corrected. FDA is not reporting that the firms were ever out of compliance or the length of time that the feed ban was violated. Lastly, inspection results are largely based on a review of paper documents and a visual inspection, with little or no feed testing. Given these data concerns and compliance unknowns, we believe that FDA's data should not be used to project industry

compliance and, anytime those data are cited, they should be reported in a complete and accurate context.

3. FDA agrees that there are industry sectors (such as transporter and animal feed salvagers) that need to be assessed to determine their potential risk to U.S. cattle. In fact, FDA acknowledges that there are millions of firms potentially subject to the feed-ban rule. At the same time, FDA implies that it has identified all high-risk firms. FDA has no basis for that assertion. The example we suggest in this report is one way of identifying additional firms that we observed during our review. FDA identified other approaches that its districts used to identify other firms. We believe that any approaches FDA identifies as useful should be applied uniformly across all FDA districts. We included information in the report on how FDA plans to use the \$8.3 million it received in the 2005 budget. We also revised the report to include FDA's estimate of the number of firms that feed cattle and other ruminants and revised the recommendation in recognition that it may be impossible for FDA to identify all firms subject to the feed-ban rule.
4. FDA suggests that requiring notification would take significant resources. The cost of the notification program will depend on the requirements FDA puts in place. In developing the program, FDA could target the notification to firms that pose potentially high-risk for exposing cattle feed to prohibited material. According to FDA, of the 14,800 firms it has inspected, about 570 renderers, protein blenders, and feed mills comprise the high-risk firms subject to notification because they manufacture or process prohibited material. While we believe there may be more firms that fall into this group, it should not be a significantly larger number. If it is significantly larger, that is something FDA needs to know. Furthermore, requiring industry to self-report is another mechanism that would help FDA identify firms and oversee compliance. Finally, FDA has registration requirements in place for medicated feed firms and for food facilities, and could draw on its experience with those programs for developing a notification program for firms subject to the feed-ban rule.¹ Because firms can change their practices over time, we believe it is important that firms notify FDA whenever such changes occur.

¹The registration requirement for food facilities is provided for in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188; 116 Stat. 594 (2002).

5. While we agree that the current test methods have certain limitations, we believe that testing can be a valuable tool for helping FDA oversee compliance with the feed ban. FDA maintains that, because the current test methods cannot differentiate prohibited material from exempt material, they cannot be used to verify the presence or absence of prohibited material or to confirm the adequacy of cleanout measures. However, states told us that they are using tests for these purposes. Moreover, FDA is currently testing finished feed and using the test results, together with follow-up inspections, to determine whether the feed ban had been violated. We believe tests would help inspectors who now rely on only paperwork review and visual examination to determine the adequacy of cleanout procedures. Tests would also be useful for vegetable-based cattle feed, where detecting the presence of animal protein would indicate a violation. We revised the recommendation to recognize that FDA may elect to use other test methods in addition to feed microscopy and polymerase chain reaction (PCR). With respect to FDA's sampling of finished feed, the 660 samples FDA tested were not collected during feed-ban compliance inspections. We plan to report later this year on FDA's sampling of finished feed.
6. We agree that FDA's current test methodology will not allow it to use test results alone to verify feed-ban violations. However, testing combined with follow-up inspections would allow FDA to be in a better position to generalize about compliance with the feed-ban rule if FDA developed a random sample methodology for inspectors to use for sampling finished feed and feed ingredients. (Also see comment 5.)
7. After clarifying FDA's comment with an attorney in FDA's Office of the Chief Counsel, we revised the report and the recommendation to delete references that FDA should encourage firms to include a cautionary statement on feed exports that may contain prohibited material. We believe that it would be more prudent for FDA to focus its efforts on obtaining statutory authority to require that the cautionary statement be used on such exports.
8. We revised the recommendation to clarify that FDA should be alerting USDA and the affected states whenever inspectors discover that cattle may have consumed feed with prohibited material.
9. Based on the inspections we observed and the 404 inspection reports that we reviewed in detail, we believe that inspector activities during feed-ban compliance inspections are driven by the checklist

items/questions on the BSE inspection form. Therefore, we believe the checklist should include specific questions to prompt inspectors to examine vehicles and firms' cleanout procedures on every inspection.

10. As noted in the report, FDA believes that it provides the inspection results in a transparent, complete, and accurate context. FDA notes that the BSE inspection data posted on its Web site "allows the user to analyze the data, in a multitude of ways, to provide their own contextual reference." Our concern is precisely that the data are being analyzed and interpreted in an erroneous context. Specifically, when FDA and industry used those data to assert a 99 percent compliance rate with the feed ban, they took that information out of context. While FDA's calculation of compliance by a subset of regulated industries may in fact be quite high, FDA's data are not sufficient to make that projection for all regulated industries because of the many problems we cite in the report. Specifically, FDA does not know the status of compliance for firms that have never been inspected or those that have not been reinspected in years. FDA also does not know if a firm that it previously inspected and classified as low-risk has started using prohibited material; and FDA reclassifies a firm in the database from "out-of-compliance" to "in-compliance" when it corrects a violation—even when the violation was serious and long-standing. Lastly, inspection results are largely based on a review of paper documents and a visual inspection, with little or no feed testing. Given these data concerns and compliance unknowns, FDA's data should not be used to project industry compliance and, anytime those data are cited, they should be reported in a complete and accurate context.

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