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Ranking Democratic Member
Committee on Agriculture, Nutrition, and Forestry
United States Senate

The Honorable Thad Cochran
United States Senate

The Honorable Richard J. Durbin
United States Senate

Subject: *Mad Cow Disease: An Evaluation of a Small Feed Testing Program FDA Implemented in 2003 With Recommendations for Making the Program a Better Oversight Tool*

In 1997, the Food and Drug Administration (FDA) banned the use of most proteins derived from mammals (referred to as prohibited material) in feed intended for cattle and other ruminants.[1] The feed-ban rule is one of the primary actions taken by the federal government to protect U.S. cattle from bovine spongiform encephalopathy (BSE),[2] commonly known as mad cow disease, which is believed to be spread through feed that contains malformed protein found in certain tissue—particularly brain and central nervous system tissue—of BSE-infected animals.[3] Earlier this year, mad cow disease was found for the first time in a 12-year old animal born and raised in the United States.

In January 2002, we reported on the effectiveness of federal actions to prevent the introduction and spread of BSE in the United States and identified a number of areas where improvements were needed to strengthen FDA's oversight of firms in the feed

[1]Ruminants 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, "cattle" refers to cattle and all other ruminant animals and "cattle feed" refers to feed for cattle and other ruminant animals.

[2]21 C.F.R. §589.2000.

[3]Adding protein (derived from animals or plants) to feed is a common nutritional practice used to speed animal growth.

industry.[4] In February 2005, we issued a follow-up report that examined the effectiveness of FDA's actions since the 2002 report to ensure industry compliance with the feed-ban rule and protect U.S. cattle from BSE.[5] Our report concluded that while FDA has taken a number of positive steps, its processes still have room for improvement. Our February 2005 report also noted that FDA had begun a small, discrete feed testing program in August 2003. We reported that we would provide information on this new feed testing program, which FDA described as a unique effort, once FDA provided us with data on the feed tests. FDA later gave us the information we required to examine those feed testing activities. Accordingly, this report assesses FDA's small feed testing program and examines the extent to which this feed testing program helps FDA better assure industry compliance with the feed-ban rule. This report is the final component of our follow-up work on FDA's BSE prevention efforts.

FDA established the feed testing program in an assignment memorandum issued in August 2003, entitled *Assignment Memorandum—Sample Assignment for Domestic Products*, which contained instructions for implementing the program. The purpose of the feed testing program was to collect and analyze cattle and other types of animal feed and feed ingredients to determine whether feed that could be fed to cattle might contain material prohibited by FDA's feed-ban rule. Under the program, FDA collected 641 feed samples through the end of fiscal year 2004 and planned to collect 900 feed samples during fiscal year 2005.

The 2003 guidance gave FDA's district offices responsibility for collecting samples and submitting them to an FDA laboratory where analysts test the samples using a procedure called feed microscopy—a visual (microscopic) examination for potentially prohibited material, such as particles of bone, hair, or muscle fiber from certain animals. If an analyst detects what appears to be prohibited material, the findings are confirmed by a second analyst. According to FDA officials, some samples were tested using a more specialized method called polymerase chain reaction (PCR), a test that FDA has been piloting, which can differentiate ruminant DNA from other animal DNA.[6]

The guidance noted that because FDA had designated a number of cattle-derived exemptions to the feed-ban rule, including blood, milk protein, and plate waste, the laboratory tests could not definitively determine violations but, rather, could identify potential violations. The guidance directs the districts to conduct follow-up reviews on each potential violation to determine whether the facility represented by the sample actually violates the feed ban. On the basis of the follow-up reviews, the districts assign final compliance determinations—that the facility where the sample was collected has complied with or has violated the feed-ban rule.

In June 2005, FDA issued a directive that all feed sample analysis and follow-up actions

[4]GAO, *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).

[5]GAO, *Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness*, GAO-05-101, (Washington, D.C.: Feb. 25, 2005).

[6]The PCR test works by aiding in the differentiation of mitochondrial DNA between animal species.

be recorded in FDA's central data system—the Field Accomplishments and Compliance Tracking System (FACTS)—and that districts complete follow-up reviews of potential violations within 30 working days. In July 2005, FDA issued a revised assignment memorandum that, among other things, enhances the testing protocol by adopting the PCR test for sample retesting and directs districts to provide sufficient narrative explanation in FACTS to explain their final determination on samples that laboratories identify as potential violations.

For the purpose of this report, we use the term "feed testing program" to distinguish the samples FDA collected for the feed-testing assignments from samples FDA and states collected in conjunction with routine BSE inspections. We included only the samples that FDA collected for the assignments. To examine the extent to which FDA's feed testing program provides better assurance of industry compliance with the feed-ban rule, we reviewed FDA's data on 1,206 samples collected through June 2005. We identified 989 feed samples collected by FDA's district offices and analyzed by FDA laboratories between August 2003 and June 2005, under the feed testing assignment/program implemented under the August 2003 guidance document. We compared sample collection, analysis, and follow-up with the program instructions in the August 2003 assignment memorandum. In order to assess FDA's timeliness in analyzing feed samples and to determine results of these analyses, we analyzed data on feed sample collection and laboratory analysis maintained in FACTS on the 989 feed samples. In order to assess the types of follow-up activities carried out by the districts and the basis for their final determinations on potential violations, we obtained and analyzed additional electronic files from FDA districts and discussed those activities and determinations with officials in the 19 FDA district offices. We also obtained detailed district-specific data and information on sample collection, follow-up, and enforcement activities in interviews with the officials in the 19 FDA district offices and discussed this information with FDA headquarters officials. To assess the reliability of the FACTS data, we analyzed the feed sample records in this database as of June 7, 2005. We analyzed the data to identify problems with completeness, accuracy, or timeliness of data entry, and reviewed system documentation on controls. We determined that the data were sufficiently reliable for the purposes of this report. The testing program data assessed for this report, including documentation in FACTS, spreadsheets maintained by individual district offices, documents describing district follow-up actions for individual samples, and all written guidance documents, were provided in response to our specific requests for all such documentation and data related to the feed testing program. Finally, we examined the feed testing program guidance that FDA provided in the June 2005 field management directive and the July 2005 assignment memorandum and compared it with the instructions and guidance FDA provided in the August 2003 memorandum. We performed our work from February through August 2005 in accordance with generally accepted government auditing standards. Our work included an assessment of FDA's feed testing program data reliability and internal controls.

Results in Brief

The feed testing program is a small part of FDA's BSE oversight effort and is one of several methods FDA uses to monitor for compliance with the feed-ban rule. However,

several weaknesses in the design and implementation of the feed testing program need to be addressed to improve its effectiveness. Specifically, under the program guidance,

- FDA did not require districts to document their follow-up reviews or the basis for their final determinations on samples that the laboratories identified as potentially containing banned protein products. Although the districts may have conducted rigorous follow-up and exercised sound judgment, the basis for their decisions cannot be reviewed and confirmed.
- For nearly half the 989 samples, FDA took longer than 30 days from the date the sample was collected until the date the laboratory completed its analysis—including 21 samples that took longer than 100 days. This extended period does not include the time FDA's districts would have spent following up on samples that indicated potential violations. FDA and industry agree that cattle feed is consumed very quickly. By the time FDA conducted its follow up to determine whether a violation had occurred, the feed may have been consumed.
- FDA managers in headquarters did not adequately oversee the feed testing program. Specifically, FDA managers did not receive periodic reports or have other oversight controls in place to assure that the program was implemented correctly. Moreover, FDA did not identify intended program goals and, as a result, does not know whether or to what extent the feed testing program is contributing to the agency's BSE oversight efforts.

FDA's June 2005 directive and July 2005 revised instructions—issued nearly 2 years into the program—includes (1) a requirement that follow-up actions and compliance determinations be fully documented in FDA's centralized FACTS compliance tracking system with sufficient explanation to allow the reader to understand the basis for the decision and (2) a time limit for districts to complete follow-up reviews.

To ensure that the feed testing program contributes to FDA's BSE oversight efforts, we are recommending that FDA (1) fully implement the June 2005 field management directive and July 2005 assignment memorandum, (2) assure that districts and laboratories adhere to time limits on collecting samples, completing sample analysis, and carrying out follow-up activities to minimize cattle's exposure to potentially contaminated feed, and (3) require sufficient oversight by headquarters managers to assure the program is achieving its intended goals.

In commenting on a draft of this report, FDA expressed concern that GAO was issuing a report that focused on one small aspect of FDA's BSE oversight efforts. We agree that it is a small component of FDA's overall efforts, but it vies for FDA's limited BSE oversight resources. Furthermore, as we pointed out in our more comprehensive February 2005 report, we looked at this small program separately because FDA did not provide program data in time for its inclusion in the broader report. FDA also disagreed with two of our recommendations in a draft of this report: that it set a time period for laboratories to complete sample analyses and that headquarters managers exercise sufficient oversight to assure the program operates as intended. FDA indicated that it had some target timeframes for laboratories. Because we could not pinpoint where delays were occurring, we revised our recommendation to address the need to minimize overall

time—from sample collection through analysis and follow-up activities—in order to minimize cattle's exposure to potentially dangerous feed. With regard to our recommendation for better management oversight, FDA disagreed with our assertion that the program was not sufficiently monitored and noted the activities its managers have undertaken. We modified that recommendation to clarify what we believe is needed in terms of management oversight.

Background

BSE is an always fatal neurodegenerative animal disease, first identified in 1986. The disease has been found in cattle in 26 countries, including the United States, which discovered its first native-born case in a 12-year old cow in June 2005. The agent believed to be responsible for BSE is a malformed protein found in certain tissue—particularly brain and central nervous system tissue—of BSE-infected animals. Cattle contract BSE by eating feed derived from the remains of an infected animal. Scientists also generally believe that a rare but fatal disease in humans—known as variant Creutzfeldt-Jacob Disease—is linked to eating products containing cattle tissue contaminated with the malformed protein. 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.

Under FDA's 1997 feed-ban rule, firms in the feed industry must (1) label feed and feed ingredients that contain or may contain most proteins from most mammals (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 firms handle cattle feed and feed ingredients (in the same facility) as well as material intended for other animal species that is prohibited in cattle feed, and (3) maintain records for 1 year so that feed and feed ingredients that contain or may contain prohibited material can be tracked from receipt through disposition.[7] Firms that transport both types of materials also must have procedures to prevent commingling.

The feed ban prohibits the use of certain mammalian proteins in the feed for cattle and other ruminants, such as sheep and goats; however, the material prohibited for use in cattle feed can be used in pet food and in feed for poultry, swine, horses, and other nonruminant animals. In addition, FDA designated a number of cattle- and other animal-derived items as exempt from the feed-ban rule and, hence, allowed in cattle feed. The exempt items include blood and blood products, plate waste, gelatin, and milk and milk proteins.[8] In addition, poultry litter (composed of poultry waste material, bedding, and

[7]The feed-ban rule is based on FDA's authority to regulate food additives, 21 U.S.C. §§ 321(s), 348, as well as other authorities.

[8]Plate waste is discarded meat and other food offered for human consumption from institutions, restaurants, and other dining facilities, which are 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.

spilled feed that is used as a protein source) is allowed in cattle feed.[9] Consequently, the presence of animal protein in a feed sample may or may not indicate a violation of the feed-ban rule.[10]

Under the risk-based inspection approach that FDA adopted in 2002, FDA has designated firms that manufacture, blend, and otherwise directly process with prohibited material as posing the highest risk for potentially exposing U.S. cattle to BSE. Firms that do not process with prohibited material are designated as posing a lower risk. FDA documents the results of BSE inspections in the FACTS compliance data system and periodically posts inspection results on the FDA Web site.

According to the August 2003 assignment memorandum implementing the feed testing program, the program objective was to "collect and analyze domestic feed, feed ingredients and other animal feed products for the presence of animal tissue using the feed microscopy method to monitor for compliance with [the feed-ban rule.]" The memorandum instructed districts to (1) select samples from animal feed, feed ingredients, and other animal feed products, such as medicated feed; (2) collect at least 50 percent of samples from products intended for ruminants; (3) select products that are labeled as containing animal protein but do not have a caution statement that they not be fed to cattle, which is required by the feed-ban rule; (4) include samples from feed that does not list mammalian protein in their name or ingredients; and (5) select each sample from a different source, processor, or manufacturer, if possible. In addition, FDA officials told us samples were being taken from "finished" feed—sold in bags or bulk—and that the testing program would give FDA an additional way to review products in the marketplace.

The August 2003 assignment memorandum assigned the district offices responsibility for regulatory and administrative follow-up of laboratory findings. It directs districts to obtain additional information on samples that the laboratories classify as identifying potential violations through reviews of firms' records, trace-back inspections to suppliers, and interviews with individuals in the chain of receipt and use of materials in the sampled feed. When districts confirm a violation, the guidance directs districts to remove the feed or feed ingredients from distribution, either by voluntary recalls or by seizure. According to the guidance, decisions to take additional enforcement actions, such as issuing warning letters, depend on the history of the firms, the scope of the violations, and the source of the prohibited material.

In May 2004, FDA headquarters conducted an internal evaluation of the feed testing program based on a review of sample collection and laboratory analysis information on samples collected and testing in the first 8 months of the program. That evaluation did not include information on follow-up reviews by the districts. In May 2005, FDA's Center for Veterinary Medicine reported that FDA follow-up reviews at feed mills and elsewhere

[9]FDA has published two advance notices of proposed rulemaking requesting comments and information revising the ban to, among other things, end most of the exemptions.

[10]In September 2005, FDA announced that it would propose regulations that parallel regulations that Canada recently announced, banning at-risk tissue—brains, spinal cords, and other parts that may carry mad cow disease—from feed for all animals including chicken, pigs, and pets.

in the feed chain revealed a high level of compliance with the feed-ban rule.[11]

The August 2003 assignment memorandum instructed the districts to collect a total of 600 samples through the end of fiscal year 2004; in fact, FDA collected 641 feed samples in that period. Enclosure I shows the number of feed samples assigned to each district and the number collected and analyzed through the end of fiscal year 2004 and for fiscal year 2005.

The Feed Testing Program Has Not Provided FDA Additional Assurance of Compliance with the Feed-Ban Rule Because of Weaknesses in Its Design and Implementation

The effectiveness of FDA's feed testing program has been limited by three design and implementation weaknesses. First, in designing the program FDA did not require districts to document their follow-up activities on samples that potentially violated the feed-ban rule or the basis for their final compliance determinations of those samples. Second, it was designed and implemented without time frames for promptly collecting and analyzing samples and following up on test results. Finally, FDA headquarters managers did not maintain adequate oversight responsibility for ensuring the program met the intended goals. FDA's June 2005 directive and July 2005 revised guidance address some of these concerns but will be useful only when fully implemented.

FDA's Districts Have Not Documented Follow-up Activities or the Basis for Their Determinations on Feed Samples

FDA's districts may have conducted rigorous follow-up and exercised sound judgment. However, they did not document their follow-up actions and the basis for their compliance determinations on whether firms violated the feed-ban rule because FDA did not require districts to clearly document those activities and decisions. As a result, the basis for their decisions cannot be reviewed and confirmed. Without this documentation, FDA has no assurance that the districts' actions were thorough and correct. FDA laboratories identified 215 of the 989 samples we examined as identifying potential violations. Based on their follow-up reviews, however, the districts determined that 214 samples did not show violations—that only one of the firms chosen for obtaining a surveillance sample violated the feed-ban rule (see table 1).

[11]*FDA Center for Veterinary Medicine Using the Science and Law to Protect Public and Animal Health, Annual Report Fiscal Year 2004, October 1, 2003 – September 30, 2004.* Rockville, MD: May 2005.

Table 1: Classification of 989 Feed Samples by FDA Laboratories and Districts, by Feed Type, August 2003 through June 2005

Type of feed or ingredient sampled	Number of samples	Number of samples laboratories classified as identifying potential violations	Number of samples districts classified as demonstrating violations of the feed-ban rule	Enforcement action taken
Feed or ingredients intended for cattle	662	141	1	1 warning letter
Feed or ingredients that could be fed to cattle or other animals (no indication that feed should not be fed to cattle)	242	44	0	None
Feed or ingredients intended for animals other than cattle	85	30	0	None
Total	**989**	**215**	**1**	**1**

Source: GAO analysis of FDA data.

The one sample FDA determined demonstrated a violation of the feed-ban rule was from cattle feed collected at a feed mill. The laboratory classified the sample as identifying a potential violation because it contained cattle hair. The label indicated that the feed contained poultry meal. The district's follow-up review determined that the renderer that supplied the poultry meal to the feed mill had previously processed prohibited material and failed to use adequate clean-out procedures to prevent commingling or cross-contamination with the ingredients intended for cattle feed. FDA issued a warning letter to the renderer for not maintaining adequate procedures or labeling the product with the required cautionary statement that the ingredients not be fed to cattle or other ruminants.

We were unable to independently verify the follow-up reviews on other potential violations or confirm the districts' final compliance determinations of samples, because the documentation supporting the districts' determinations was lacking or incomplete. When we asked FDA for this information, FDA acknowledged that it did not require the districts to document their follow-up activities. FDA headquarters contacted its districts and told them to reconstruct an accounting of their follow-up actions and final compliance determinations. Thus, FDA compiled this information several months after the fact for most samples. The information we received was unclear and did not contain sufficient sample-specific information. Table 2 summarizes the type of district follow-up activities compiled by FDA.

Table 2: District Follow-up Action on Samples Identifying Potential Violations by the Laboratories

District follow-up action	Number of samples	Percent
No inspection or regulatory follow-up for this sample	82	38
An investigation or follow-up inspection occurred to resolve findings	13	6
A routine inspection was either scheduled or has occurred since the analysis of the sample	71	33
A warning letter was recommended by the district for at least one firm associated with the sample	4	2
Other action taken or action is still pending	15	7
There was no indication as to the type of follow-up conducted	30	14
Total	**215**	**100**

Source: GAO analysis of FDA data.

Likewise, the narrative information that FDA compiled from the districts on their final compliance determinations, which we summarize in table 3, does not give sufficient information to verify the basis for those determinations.

Table 3: District Compliance Determinations on Samples Identifying Potential Violations by the Laboratories

District compliance determination	Number of samples	Percent
Classified as in compliance through a review of lab results and previous inspection records of the firm	77	36
Classified as in compliance through a review of lab results and accompanying ingredient statements	74	34
Classified as in compliance through a review of lab results and at least one inspection conducted after analysis of this sample was completed	29	13
Classified as in compliance, but no indication given by FDA as to how this decision was made	10	5
Possible mislabeling or adulteration involving nonexempt material—official action is possible.	8	4
Follow-up is still pending	12	6
Classification was not indicated by FDA	4	2
Not a BSE-related finding	1	0
Total	**215**	**100**

Source: GAO analysis of FDA data.

In order to verify the basis for their determinations, districts must be able to provide clear and sufficient information for a reviewer to understand the decisions made and the reason for making those decisions. That is, when a district follows up on a sample that a laboratory has classified as evidencing a potential violation, the district would describe the specific evidence it uses to reach a determination that a firm has not violated the feed-ban rule. FDA's July 2005 guidance recognizes the importance of this critical step and directs the districts to provide sufficient narrative explanation in FACTS to allow an FDA manager to understand the basis for those decisions. If, for example, the analyst observes particles of bone, tissue, or hair in cattle feed, and the district is relying on

records from a recent BSE inspection, we would expect the district to provide a detailed description of the animal material the firm used and the date it used that material to manufacture the feed. This description would have to fully explain what the laboratory observed. If information from a recent inspection is not available, we would expect FDA to conduct a follow-up inspection at the firm and describe the documents, such as dated invoices, that verify the type of animal material used that fully explains what the laboratory observed.

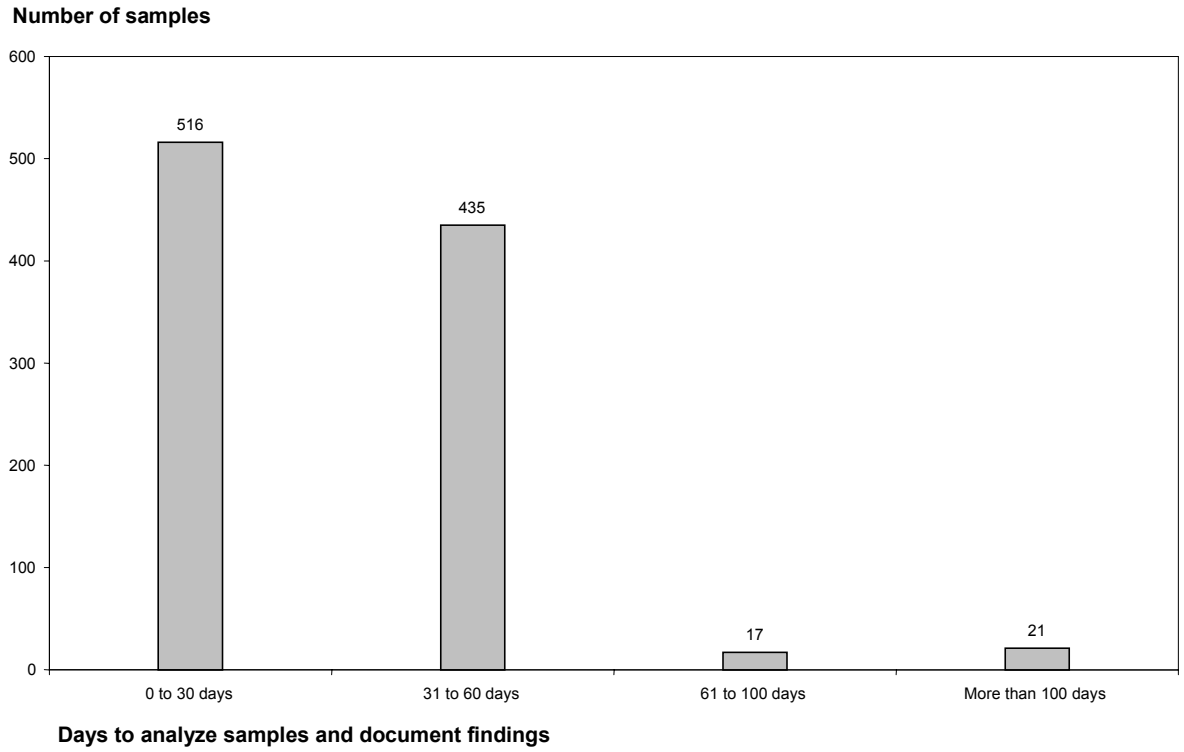
When we met with FDA officials in September 2005, they acknowledged that headquarters and field managers did not have an easily accessible, uniform method for tracking districts' follow-up actions and compliance determinations that would enable them to perform thorough oversight and analyze trends in the program. Officials stated that the new June 2005 directive should alleviate these shortcomings and that FDA will make further changes if managers determine that the directive does not address all of the weaknesses.

FDA Did Not Ensure That Samples Were Promptly Sent to Laboratories and Analyzed and That Potential Violations Were Quickly Followed Up

FDA's program guidance did not include timeframes for ensuring that laboratories analyzed samples and districts follow up on test results promptly; as a result, FDA had no assurance that these activities were carried out expeditiously to minimize the risk that cattle would be fed potentially contaminated feed. After FDA received the draft report for comment, it informed us that laboratories are to complete their analysis of samples taken under the feed testing program within 20 working days, although this timeframe is not in the August 2003 program guidance for laboratories. FDA could not provide data we requested to determine the amount of time that samples were undergoing analysis or the time districts spent in following up on potential violations and reaching a final determination because it does not track this information.

However, FDA did provide the date each sample was collected and the date the laboratory reported the results of its analysis to the district because the districts and laboratories were entering that information into the FACTS compliance tracking system. In analyzing these data, we found that for nearly half of the samples we examined (473 of 989), more than 30 days elapsed before the laboratories reported sample findings to the districts. That included 38 samples for which more than 60 days—and in some cases more than 100 days—elapsed before the laboratory findings were reported to the districts (see fig. 1).

Figure 1: Number of Days for FDA Laboratories to Analyze Feed Samples and Report to Districts from Date of Collection, August 2003 through June 2005



Source: GAO Analysis of FDA Data.

The districts initiated follow-up activities on potential violations of the feed-ban rule after the laboratories reported their analyses. However, FDA did not provide consistent information on the timeliness of district follow up actions because they were not tracking this information. Therefore, we could not determine how much more time passed before districts took follow-up actions on the 215 samples that the laboratories identified as potentially demonstrating violations of the feed-ban rule.

According to FDA and industry officials, however, cattle feed is consumed very quickly. Because FDA did not include timeframes in the August 2003 guidance for laboratories to analyze samples and for districts to follow up on samples identifying potential violations, by the time inspectors determined that cattle feed was contaminated, all the feed in question could have been consumed by cattle. In commenting on a draft of this report, FDA indicated that it plans to evaluate the number of days that laboratories are spending on analyzing feed samples as those data are compiled.

FDA Headquarters Managers Did Not Exercise Adequate Oversight of the Feed Testing Program

FDA's managers in headquarters designed the feed testing program and issued the August 2003 assignment memorandum. However, those managers did not exercise oversight once the program was implemented. Specifically, FDA managers had no controls in place to ensure that the August 2003 guidance was consistently followed, that

results were carefully tracked, and that the program was operating as intended and achieving its intended goals. FDA did not identify program goals and, as a result, does not know whether or to what extent the feed testing program is contributing to the agency's BSE oversight efforts. In past reports, we have stressed the importance of performance measures as critical internal control standards that enable federal agencies to compare and analyze actual performance data against expected or planned goals for their activities and programs.[12] However, FDA had no such controls in place to compare and analyze feed testing activities carried out by its laboratories and districts. Under the Government Performance and Results Act of 1993, agencies must use outcome-oriented goals and performance measures that assess results, effects, or impacts of a program or activity compared with its intended purpose.[13] Without such measures, FDA cannot assess whether its feed testing efforts achieved the intended results or how well districts and laboratories collected and analyzed samples and followed up on samples that potentially violated the feed-ban rule.

Following are some examples where laboratories and districts did not implement the 2003 assignment consistently and FDA headquarters managers did not have oversight in place to discover these inconsistencies:

- FDA laboratories classified 29 samples as "in compliance" that analysts described as containing mammalian protein from an unidentifiable source. Based on the August 2003 guidance, however, analysts should have classified these samples as identifying potential violations, thus flagging them for district follow-up.
- One of the six FDA laboratories continued to misclassify samples as demonstrating definite violations—a classification that current testing technology does not support—after the May 2004 evaluation revealed that this type of misclassification was occurring.
- Eighteen districts collected nearly all samples from firms that had previously undergone a BSE inspection, while one district collected samples at retail stores that did not manufacture feed and typically had not undergone a BSE inspection. FDA's risk-based inspections target firms that manufacture, blend, and otherwise directly process with prohibited material; however, the 2003 assignment instructions appear to focus on feed samples collected at the retail level and FDA officials told us that samples collected for the feed testing program were to be taken from finished feed sold in bags or in bulk, which would give FDA an additional way to review products in the marketplace.
- Laboratories reported that labels and ingredient lists were missing for 28 of the 215 samples with potential violations, although the August 2003 assignment instructed districts to submit these items with samples. The July 2005 assignment continues to instruct districts to submit labels with samples.

[12]See GAO, *Results-Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, GAO-04-38, (Washington, D.C.: March 10, 2004); *Managing for Results: Strengthening Regulatory Agencies' Performance Management Practices*, GAO/GGD-00-10 (Washington, D.C.: Oct. 28, 1999); *Standards for Internal Controls in the Federal Government*, GAO/AIMD-00-21.3.1, (Washington, D.C.: Nov. 1999).

[13]Pub. L. No. 103-62, 107 Stat. 285 (1993).

FDA headquarters did not have oversight mechanisms in place to monitor the feed testing program nor performance indicators to compare program results across laboratories and districts to detect these implementation differences.

In addition, headquarters had no controls in place to discern that districts were not recording or tracking sample follow-up actions and compliance determinations. Although its FACTS compliance tracking system contains data fields for documenting a narrative explanation of what action was taken, the rationale for the action, the final district classification, and the date of the decision, the 2003 assignment did not direct the districts to use FACTS and FDA's oversight did not detect and correct this until the June 2005 directive and July 2005 revised assignment. The FACTS compliance tracking system is the centralized database that FDA implemented agency wide for the expressed purpose of capturing this information.

Furthermore, after FDA headquarters conducted the internal evaluation in May 2004, it did not act to implement internal controls to ensure that the testing program would achieve its intended goals and correct the problems identified in that review. The internal review looked at 370 samples taken during the first 8 months of the program. The report identified 70 samples classified by the laboratories as potentially in violation of the feed ban, including 42 samples of feed intended for cattle. FDA based its evaluation on the laboratories' descriptions and any label or ingredient information submitted with the samples, but did not consider any district follow up on laboratory findings. The evaluation "encouraged" the districts to follow up on 14 of the 42 cattle feed samples and 26 samples from feed intended for other species that could include prohibited material. FDA headquarters did not question how the districts addressed the review findings.

The feed testing program cannot provide FDA with additional assurance of compliance with the feed ban unless headquarters exercises adequate oversight and implements internal controls to address these program weaknesses.

New Procedures Address Some Feed Testing Program Weaknesses

FDA officials have acknowledged weaknesses in the August 2003 memorandum and told us that the June 2005 directive and July 2005 revised assignment memorandum are intended to address those problems.

FDA's June 2005 directive requires, among other things, that

- all feed sample analysis and follow-up actions are documented accurately and in a timely fashion in the agencywide FACTS compliance tracking system;
- program managers at headquarters, regions, districts, and laboratories implement internal audit procedures and controls to verify that sample analysis and follow-up actions are timely and accurately documented in FACTS; and
- districts complete and document follow-up actions within 30 working days following receipt of sample results from the laboratory.

The July 2005 revised program instructions clarify sample selection criteria and require, among other things, that

- laboratories use PCR to verify samples that indicate the possible presence of mammalian bone or hair, and
- districts document their assessments of samples found to be in potential violation of the feed ban and their final determinations with sufficient narrative explanation to allow a reviewer to understand the basis for their decisions.

The new directive and instructions went into effect immediately. FDA officials told us that the districts are entering the required information in FACTS for all samples followed up in fiscal year 2005. However, if districts enter the same type of information that they provided to us without, for example, citing the specific documentation used and actions conducted to reconcile laboratory findings, then these additions to FACTS may not be useful for oversight.

Conclusions

FDA's June 2005 directive and the July 2005 revised assignment include important new controls that address many of the weaknesses we found in the feed testing program. However, the new directive and guidance will be useful only when FDA ensures their full implementation. One important requirement in the directive and guidance—for districts to document their follow-up activities and compliance decisions—will allow FDA to use the program results to supplement the agency's other BSE oversight activities. FDA's districts and laboratories believe they have implemented the feed testing program diligently and thoroughly, using their best professional judgment. That notwithstanding, until the districts' actions are documented in a fashion that fully explains the basis for their compliance determinations, FDA cannot verify and hence cannot confidently rely on the testing program results.

Another important requirement in the new directive is the addition of a 30-day time limit for districts to complete their follow-up actions and make final compliance determinations for feed samples that identify potential violations of the feed-ban rule. That new guidance notwithstanding, we remain concerned about the overall time frame. We found that more than 30 days elapsed between the date samples were collected and the date laboratories completed their analysis for nearly half the samples, and that these two steps took more than 100 days in some instances. Only then would districts have begun their follow-up activities. However, both FDA and industry agree that cattle feed is consumed very quickly. Consequently, by the time FDA completes its follow up activities and determines that a violation has occurred, the feed may have been consumed. We believe that both the districts and the laboratories need to carry out their feed testing program responsibilities promptly to minimize cattle's exposure to potentially contaminated feed.

While FDA's new assignment instructions recognize the importance of management accountability, they do not include specific oversight requirements that will address the

deficiencies we identified. Even though the feed testing program is small, adequate management oversight of the program is critical, because the resources FDA spent on the program since August 2003 came directly from the agency's limited BSE oversight funding. If they exercise appropriate oversight, FDA headquarters managers can help ensure that future results of the feed testing program will be reliable, and that BSE resources will be carefully spent. In this regard, we believe that periodic reports using FACTS data would be useful. Other internal controls may also provide useful management oversight, and FDA would benefit if it developed performance indicators and set goals for its managers to use to determine whether and to what extent the feed testing program is contributing to the agency's BSE oversight efforts.

Finally, feed testing has the potential to be an important tool in FDA's feed-ban oversight arsenal as technology improves, and we believe FDA would benefit by encouraging the development, testing, and implementation of new feed testing technologies. PCR is a better tool than feed microscopy, and the capabilities of PCR are being refined and improved. As more accurate and effective PCR and other feed testing technologies emerge, the value of feed testing to FDA's BSE oversight will increase.

Recommendations for Executive Action

To ensure that the feed testing program is a useful tool for helping FDA oversee industry compliance with the feed-ban rule, we are recommending that the Commissioner of FDA take the following three actions:

- Fully implement the June 2005 field management directive and July 2005 assignment memorandum revising the feed testing program.
- Assure that districts and laboratories adhere to time limits on collecting samples and completing sample analysis and follow-up activities to minimize cattle's exposure to potentially contaminated feed.
- Require FDA headquarters managers to exercise sufficient oversight, with periodic reports from FACTS or other management controls, and identify appropriate performance indicators for the feed testing program, to assure that the program operates as intended and achieves its intended goals.

Agency Comments and Our Evaluation

We provided FDA with a draft of this report for review and comment. In its comments on the draft report, FDA included an overview of its BSE oversight program to put the feed testing effort in context. FDA expressed concern that we were issuing a report that focused on one small aspect of that effort. As we explained in our more comprehensive February 2005 report, we analyzed and are reporting separately on this small program because FDA did not provide program data in time for its inclusion in the broader report.

With respect to our first recommendation, FDA indicated that it plans to fully implement the June directive and July guidance. We have included this as a recommendation to help FDA maintain its momentum and attention to a program that commands a portion of its limited BSE oversight resources. With respect to our second recommendation, FDA told

us that its laboratories have a time limit of 20 working days to analyze feed samples from this program. However, FDA could not provide data to document whether laboratories were meeting this time limit and our analysis of the elapsed time for the two steps of sample collection and data analysis often showed the time spent to be excessively long—from 60 to 100 days and longer in some instances. Because the overall time frame is the period of concern, we revised our recommendation to address overall timeliness to minimize cattle's exposure to potentially contaminated feed. We believe that when FDA implements better tracking under the 2005 directive and guidance, it will have data to help determine specifically where timeliness can be improved. This will give FDA data to assess laboratory timeframes, which it indicated that it plans to do. Regarding our third recommendation for better management oversight, FDA disagreed with our assertion that the program has not been adequately monitored. However, FDA did not provide evidence that its managers received periodic reports assessing program performance or that they had other adequate management oversight controls in place. We believe that our revised recommendation, if implemented, will put FDA in a position to determine whether and to what extent the feed testing program is contributing to its BSE oversight efforts.

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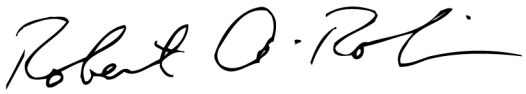
As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the date of this letter. At that time, we will send copies of this report to the congressional committees with jurisdiction over FDA and its activities; the Secretary of Health and Human Services; the Secretary of Agriculture; and the Director, Office of Management and Budget. In addition, this report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or robinsonr@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributions to this report were made by Erin Lansburgh, Assistant Director; Jeremy Manion; Lynn Musser; George Quinn; Carol Herrnstadt Shulman; John C. Smith; and Amy Webbink.



Robert A. Robinson
Managing Director, Natural Resources
and Environment

Enclosures

Number of Feed Samples Assigned and Collected and Analyzed, as of June 7, 2005, by FDA District

District	Number of samples			
	First sample assignment		Second sample assignment	
	Assigned	Collected and analyzed[a]	Assigned	Collected and analyzed, as of June 7, 2005
Atlanta	20	22	20	0
Baltimore	18	18	17	13
Chicago	58	56	29	21
Cincinnati	70	72	61	27
Dallas	58	52	94	48
Denver	20	20	26	13
Detroit	58	55	60	31
Florida	5	3	20	0
Kansas City	88	89	171	42
Los Angeles	8	38	35	3
Minneapolis	70	84	181	81
New England	5	5	9	11
New Jersey	0	0	2	0
New Orleans	20	15	18	8
New York	20	27	18	16
Philadelphia	20	20	51	15
San Francisco	20	20	60	0
San Juan	16	19	5	2
Seattle	26	26	23	17
Total	**600**	**641**	**900**	**348**

Source: GAO analysis of FDA data.

[a]We excluded samples that were collected by the districts when the analysis was not also included in the files provided by FDA.

Comments from the Food and Drug Administration

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

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 enclosed the general comments in response to the General Accountability Office's correspondence entitled, *"Mad Cow Disease: FDA Needs to Fully Implement New Procedures and Correct Other Design Flaws for the Feed Testing Program to Help Assure Industry Compliance with the Feed Ban."*

We appreciate the opportunity to review and comment on this draft correspondence before it is published, as well as the opportunity to work with your staff in its development.

Sincerely,

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

Enclosure

FDA General Comments on the Government Accountability Office's Draft Letter on *Mad Cow Disease Follow-up: Feed Testing (GAO-05-904R)*

See comment 1.

FDA values the opportunity to review and comment on the Government Accountability Office's (GAO) draft document. Even though we understand based on our exit conference discussion that some changes will be made in the draft document, our comments are based on our review of the draft provided on August 17, 2005, including the draft recommendations for executive action. We are concerned that GAO's issuance of a document that focuses on a small component of the overall BSE control program places an undue emphasis on that component's impact on the program. For that reason, FDA will present an overview of the BSE program operating in the United States, and attempt to place into perspective the role feed testing contributes to the overall program. FDA will also offer comments on GAO's three recommendations. Additionally, it is important to note that FDA spent nearly 600 (ORA and CVM) hours providing information to GAO on this supplemental study. This includes time accounted for when GAO conducted interviews with every FDA District office, as well as time spent by Headquarters' staff compiling information and responding to the 33 questions that GAO asked in order to assess if feed testing helped FDA better assure industry compliance with the feed ban.

See comment 2.

See comment 3.

GAO provided three draft recommendations for executive action. For the first recommendation, FDA appreciates GAO's recognition that the June 2005 field management directive and July 2005 BSE sampling assignment memorandum provide controls that enhance the agency's ability to evaluate the utility of this program in the future. Regarding the second recommendation, FDA disagrees that laboratory testing timeframes to complete sample analysis for domestic surveillance samples are a critical element to minimize cattle's exposure to potentially contaminated feed. Lastly, with regard to the third recommendation, FDA also disagrees with GAO's assertion that the sampling assignment was poorly implemented, and that FDA did not adequately oversee the assignment.

See comment 4.

While GAO identifies in its report that feed testing is a small component of FDA's BSE oversight effort, we believe it is critical to clarify the current perspective on the utility that feed testing plays in relation to the overall U.S. BSE control program. The U.S. cattle BSE control program consists of a multifaceted system to keep the disease from entering and spreading. The components consist of import controls on ruminant animals and animal feed, a BSE surveillance cattle testing program, an effective response to the finding of BSE positive animals, and a feed ban. This program remains a top priority for FDA, USDA, and other government agencies. While we focus on the feed ban in this discussion, we will touch on the other facets to make certain the overall control program is understood.

Import control is the critical safeguard preventing the BSE agent from entering the United States. FDA and the USDA's Animal and Plant Health Inspection Service (APHIS) work in close cooperation with Customs and Border Protection on controls related to imports of animals and animal-derived products. Imports were restricted in 1989 from the United Kingdom, and those restrictions were expanded to imports from countries where BSE has been reported, and to countries identified to be at high risk for BSE, as needed. It is important to note that testing imported feed is a valuable component of our import controls for BSE, yet the GAO did not include the import testing program in its audit or report.

See comment 5.

USDA's active surveillance program to test cattle for BSE is another element of the prevention efforts to date. USDA has tested more than 460,000 cattle from June 1, 2004 to mid-September

1

2005 and has found one BSE-positive cow. Prior to June 1, 2004, USDA's surveillance program identified an additional BSE-positive cow from Canada. In addition to its continued testing of the higher risk cattle population, USDA is planning to test a population of apparently healthy cattle over 30 months of age at slaughter.

An additional control measure is an effective and coordinated response to the finding of a BSE-positive animal. In response to the December 2003 BSE-positive animal in Washington State, FDA, USDA, and the Washington State Department of Agriculture coordinated closely in their epidemiological investigation tracing the positive cow to its farm of origin in Alberta, Canada, and in the traceforward investigation to control potentially contaminated product derived from the positive animal. A similarly coordinated response was seen in the investigation of the Texas cow that was declared positive for BSE in June 2005. Although the positive cow posed no risk to the human food or animal feed supply, FDA, APHIS, the Texas Animal Health Commission, and the Texas Feed and Fertilizer Control Service conducted an epidemiological investigation of the herd of origin, as well as a feed investigation. The feed investigation found that no feed or feed supplements used on the farm since 1997 were formulated to contain mammalian protein prohibited under the FDA Ruminant Feed Ban regulation, and that all the investigated rendering plants were operating in compliance with the regulation. This high level of coordination came about through extensive planning, including the sharing of BSE response plans and the conduct of three joint exercises with our federal and state partners to test our capabilities to respond.

Another extremely important component in the BSE control program is FDA's ruminant feed ban, which was put in place in 1997 to prevent the amplification of BSE through feed in the event that the BSE agent had been introduced into the United States. The regulation prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, found in 21 CFR 589.2000, became effective on August 4, 1997. The regulation reflected the best epidemiological knowledge at the time. FDA continues to evaluate the science related to BSE and recognizes the presence of BSE in the United States. Accordingly, FDA published jointly with USDA an Advance Notice of Proposed Rulemaking (ANPRM) in July 2004 to obtain information and comments on additional control measures being considered to further strengthen the feed ban.

To implement its feed ban regulation, FDA has put into place a Ruminant Feed Ban compliance program. The key elements of the compliance program include education of industry on the requirements of the regulation, inspection of facilities subject to the ban, and appropriate enforcement of the regulation's requirements. Since a significant portion of the animal feed industry was impacted by the new regulation, the initial focus of the compliance program was to educate both the industry and regulators about the feed ban. FDA sponsored numerous workshops attended by state veterinarians and feed control officials from all 50 States and Puerto Rico. In addition, FDA held briefing sessions with trade associations and consumer groups and has developed guidance documents to assist industry in complying with the regulation. The major implementation tool to assure compliance by regulated parties is a rigorous program of establishment inspections by FDA and state regulatory counterparts. In collaboration with state feed control officials, FDA has conducted over 37,000 inspections of renderers, feed mills, protein blenders, as well as other firms subject to this regulation such as ruminant feeders, on-farm mixers, pet food manufacturers, animal feed salvagers, distributors, retailers, and animal feed transporters. FDA routinely provides reports on its feed ban enforcement activities. Additionally, FDA posts the results of every firm inspected under the Ruminant Feed Ban program on the FDA web site. Compliance with this regulation by renderers, feed mills, and protein blenders remains very high. Furthermore, FDA has

See comment 6.

monitored recalls, issued warning letters, and taken other enforcement actions when significant violations have been documented during inspections.

The assignment to test domestic feed for the presence of prohibited material is a relatively small component of FDA's overall domestic Ruminant Feed Ban efforts. Since no test currently exists for the detection of the agent that causes BSE in feed, analysis of feed is not a means of verifying the safety of cattle feed. The substitute for the infectious agent used in all current tests is the mammalian protein prohibited under the Ruminant Feed Ban. However, the current tests used, feed microscopy and/or PCR, are not adequate methods to make compliance decisions about the presence of prohibited material since the methods have limitations and the rule has exemptions. Feed microscopy generally can only detect the presence of mammalian tissue, either through the identification of bone or hair. The present Ruminant Feed Ban allows for certain exemptions to the mammalian protein prohibition. Exempted materials include pure porcine and equine meat and bone meal, blood (from any animal species, including ruminants), gelatin, and milk protein. There is no prohibition on the use of non-mammalian proteins (e.g., poultry meal). Certain tissues, such as bone or muscle, may be present as a result of the use of exempt ingredients, such as pure porcine meat and bone meal or poultry meal. While the PCR method can detect ruminant mitochondrial DNA, it cannot differentiate between prohibited material and ingredients exempted by the feed ban, such as ruminant blood and inspected meat products which have been cooked and offered for human food and further heat processed for feed. Since neither method can differentiate prohibited material from other acceptable materials, the analytical results by themselves cannot be used to verify the presence or absence of prohibited material. The only way to determine compliance with the Ruminant Feed Ban rule is to conduct an inspection of the firm.

See comment 7.

The FDA assessment of the current weakness of the feed microscopy method, as a compliance tool, is similar to findings by the Canadian Food Inspection Agency (CFIA). CFIA conducted a recent trial on the usefulness of microscopy method for analyzing the composition of feed. CFIA found that the limitations of the microscopy method outweigh its usefulness. Further, CFIA found that physical inspection of facilities and records was necessary to determine compliance with Canada's BSE feed controls, which are nearly identical to ours. The report is available at www.inspection.gc.ca.

While CFIA came to its position after a small pilot test, FDA is still assessing the potential usefulness of feed testing of domestically produced products in FDA's long-term enforcement of the feed ban. Further, the sampling assignment is designed to be an additional way to review products in the marketplace by providing a supplemental piece of intelligence to help in selecting firms for inspection coverage under the compliance program. A positive finding from analytical testing 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 rule.

On August 18, 2003, FDA/CVM issued the first sampling assignment to the FDA field staff for the collection of 600 domestic samples, which was subsequently increased to 900 samples for the current fiscal year. The fairly recent implementation of this unique sampling assignment has involved efforts to train laboratory personnel in the techniques of feed microscopy, to provide reference samples for confirmatory comparison, and to assess proficiency in the technique by all laboratories conducting analytical testing. Based on the agency's experience derived from the initial sampling assignment, FDA issued a second assignment in July 2005 that refines

3

directions for sample collection and classification and incorporates PCR for additional analysis of samples found by the feed microscopy method to contain animal tissue.

It is important to note that the scientific enhancements in this latest assignment are based on research the agency has conducted on feed testing methodology. In 2001, FDA published the results of its first method validation trial using a PCR-based approach to detect bovine materials in animal feed. This method was successfully validated at a detection level of 0.125 percent bovine meat and bone meal, on a weight-to-weight (w/w) basis. While a robust method, it was labor-intensive to perform, requiring the analyst to prepare all the necessary reagents. The 24 hours needed to analyze a sample further limited the number of samples an analyst could process.

See comment 8.

Subsequently, efforts were initiated to develop a second-generation PCR-based assay using a DNA extraction method that was easier to perform than the one used in the validated, first-generation PCR-based method. Using a commercially available DNA Forensic Kit, a suitable method was developed to permit extraction of DNA from animal feed and feed ingredients. This method significantly shortened the time required to analyze a single sample to under 8 hours, start-to-finish. In addition, because the DNA extraction portion is significantly easier to perform, the total number of samples that a single analyst can examine was doubled. The second-generation method has been successfully validated to permit detection of bovine, ovine, and porcine materials in animal feed and feed ingredients at a level of 0.1 percent (w/w basis). FDA has implemented this second-generation PCR-based assay in the enhanced sampling assignment issued in July 2005 following validation work in our field laboratories.
Both the first and second-generation PCR-based methods are conventional PCR-based methods that rely on photo documentation followed by visual interpretation of the results. These methods are at best semi-quantitative. Currently, FDA scientists are working on a third-generation PCR-based method that will use an approach called real-time PCR. Real-time PCR assays measure the amount of product being formed while the PCR process is still ongoing. There is no post-PCR processing of the test samples as is required for the first and second-generation PCR-based methods. Therefore, a real-time PCR based method will result in a further reduction in time needed to analyze the feed samples. The process involved in assessing PCR-product formation yields data that are proportional to the amount of starting DNA in the test sample, and therefore, these results are proportional to the amount of prohibited proteins in the original sample. The chemistry involved with real-time PCR permits direct addition of internal controls to ensure assay functionality. Lastly, PCR products formed during real-time PCR permit a determination as to whether or not the final PCR product was derived from the expected species (e.g., bovine) by performing a melt-curve analysis. Each PCR product will have a specific temperature at which the double-stranded DNA molecules will separate.

While feed microscopy and PCR are used by FDA and some state laboratories, these methods cannot be performed by all facilities and organizations that need to test for the absence of prohibited proteins. There are four companies that market various immunochemical test kits (antibody-based) that are simpler to use than either PCR or feed microscopy. These kits might also seem useful for FDA's purposes. However, these test kits are marketed without FDA's review and approval, as FDA does not have premarket approval authority over veterinary devices. FDA therefore initiated a research program to evaluate their performance characteristics. An essential aspect of this evaluation was the development of acceptance criteria and performance guidelines against which these tests would be assessed. An important component of these guidelines was the criteria that these tests be able to detect prohibited proteins at the same level as PCR and microscopy. To date, we have completed our initial

4

evaluation of two of these test kits and are close to completing our evaluation of a third kit. The two test kits for which we have completed our evaluation did not meet our acceptance criteria and performance guidelines; one test had an unacceptable rate of false positives (true negatives that the test deemed to be positive) and the second test kit did not have the sensitivity set out in our performance criteria.

FDA remains firmly committed to fostering the development of new technologies to better understand BSE. Future scientific research may uncover a way to definitively test for the presence of prohibited materials in animal feed or to detect the presence of the agent that causes BSE in feed. FDA will continue to evaluate and make changes to the sampling assignment to reflect current validated scientific methods.

See comment 9.

In conclusion, FDA's Ruminant Feed Ban domestic sampling program is unlike other sampling programs where analytical methods are available to detect specific pathogens, toxins, or residues that are considered adulterants in FDA regulated products. For the Ruminant Feed Ban domestic sampling and analysis assignment evaluated by GAO in this study, the analytical contribution to assurances of compliance is more limited due to the constraints of the currently available test methodologies and existing exemptions for mammalian proteins in the regulation. For this reason, FDA conducts only limited testing under this surveillance assignment (in FY'04 this assignment only accounted for approximately 600 of the over 46,000 samples collected and analyzed by FDA regulatory laboratories). The domestic sampling and analysis component of the Ruminant Feed Ban may become a more valuable tool in the future, or may be discontinued, depending on development of new technologies or methods, enhancements to strengthen the feed ban that may be instituted, and/or a better scientific understanding of the epidemiology and pathogenesis of the BSE agent in animal populations.

See comment 10.

GAO Recommendations for Executive Action

To ensure that the feed testing program is a useful tool for helping FDA oversee industry compliance with the Feed Ban rule, GAO recommends that the Commissioner of FDA take the following three actions:

- Fully implement the June 2005 field management directive and July 2005 assignment memorandum revising the feed testing program.

FDA Response:

FDA appreciates GAO's recognition that the June 2005 field management directive and July 2005 BSE sampling assignment memorandum provide controls that enhance the agency's ability to evaluate the utility of this program in the future and intends to implement the current versions or subsequent versions of these documents that are issued.

See comment 11.

- Establish timeframes for laboratories to complete sample analysis to minimize cattle's exposure to potentially contaminated feed.

FDA Response:

FDA field laboratories currently have timeframes for completing sample analyses. The timeframes are 10 business days for compliance samples and 20 business days for surveillance samples. The samples taken under the BSE feed sampling assignment are surveillance

5

samples, as opposed to compliance samples. Because import and "for-cause" samples are given priority, laboratories are sometimes unable to complete analysis of surveillance samples within 20 days.

FDA will evaluate the number of days it has taken laboratories to complete their analyses under this program and will set new timeframes, if needed. This evaluation will be completed as part of management's oversight of the implementation of the June 2005 field management directive and July 2005 sampling assignment memorandum.

GAO asserts that expedited laboratory testing will minimize cattle's exposure to potentially contaminated feed. FDA disagrees that laboratory testing timeframes to complete sample analysis for domestic surveillance samples are a critical element to minimize cattle's exposure to potentially contaminated feed. FDA relies on its overall inspection program, rather than analytical methods alone, to enforce the feed ban.

See comment 12.

- Require FDA headquarters' managers to exercise sufficient oversight, with periodic reports from FACTS or other management controls and identify appropriate performance indicators for the feed testing program to assure that the program operates as intended and achieves its intended goals.

FDA Response:

FDA disagrees with GAO's assertion that the sampling assignment was poorly implemented, and that FDA did not adequately oversee the assignment. The FACTS database was utilized in fully describing feed collection and laboratory activities. Feed collection information includes feed type, a feed description, a feed label summary, and the identity of the associated feed manufacturer and distributor. Laboratory information includes a full description of the test utilized, the observations of the analyst, and the laboratory classification of the sample results. Spreadsheets containing both types of information were generated on a weekly basis and distributed throughout FDA headquarters. These data spreadsheets were constantly examined and utilized by FDA headquarters' managers in providing feedback and education to District and laboratory personnel.

Although the spreadsheet did not contain information regarding follow-up activities, FDA headquarters was in constant communication with Districts concerning questions and issues related to sample collection and interpretation of analytical results. This oversight and communication were reflected in an improved understanding of the sampling assignment's goals by Districts and laboratories as time progressed.

See comment 13.

The experiences gained through the August 2003 sampling assignment allowed for significant improvements as represented in the revised assignment issued in July 2005. The issuance of the revised assignment was somewhat delayed until all laboratories were fully prepared to utilize the new PCR method. The recording of follow-up summaries in the FACTS database and the development of additional database reports have enhanced the ability of FDA headquarters to more effectively evaluate all aspects of activities related to feed testing efforts.

FDA notes that the assignment may again be revised based on experiences involving the incorporation of the new PCR method. FDA will continue to monitor and evaluate feed testing to determine whether it is a worthwhile component of FDA's long-term BSE prevention efforts.

6

Enclosure II

The following are GAO's comments on the Food and Drug Administration's letter received on Monday, September 19, 2005.

GAO comments

1. At our September 7, 2005, exit meeting with FDA, FDA raised concern that the draft title could be taken out of context by U.S. trading partners who would not read the report and could construe that we were talking about weaknesses in FDA's bovine spongiform encephalopathy (BSE) oversight efforts in general. We told FDA officials that we would look at the title in that light. We revised the title to better ensure that readers would realize by the title alone that the report focused on the small feed testing program that FDA started in August 2003. At the exit meeting, FDA also provided us with an untitled and undated document that FDA officials identified as a list of time frames for laboratories to complete analysis on various testing programs, including the feed testing program. The targeted time frame for the feed testing program—from receipt of sample to classifying the sample in FACTS—was 20 working days. As our report states, the time frames from sample collection to documenting the laboratory result in FACTS exceeded 30 days for 473 of the 989 samples we assessed. These included 17 samples that took from 60 to 100 days and 21 that took more than 100 days. FDA officials agreed that these time frames were unacceptable and did not challenge our analysis. FDA did not give us data on whether laboratories are meeting the 20-working day target. Also, FDA could not provide information on the time it took for districts to follow up and make a final determination on the 215 potential violations we report because it did not track those time frames. The timeliness of the entire process from sample collection to final determination is a factor that directly affects cattle's exposure. The second recommendation in our draft report initially recommended that FDA establish time frames for laboratories to complete sample analysis to minimize cattle's exposure to potentially contaminated feed. Because FDA did not provide data to assess whether the delays are occurring during sample collection, laboratory analysis, or follow-up, we revised our recommendation to address the need to minimize the overall time frame to protect cattle.

2. FDA expressed concern that we were issuing a report that focused on one small aspect of its BSE oversight efforts. We agree that the feed testing program is a small component of FDA's overall efforts, but it vies for FDA's limited BSE oversight resources. As we pointed out in our more comprehensive February 2005 report—*Mad Cow Disease: FDA's Management of the Feed Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness* (GAO-05-101; Feb. 25, 2005)—we looked at this small program separately because FDA did not provide program data in time for its inclusion in the broader report.

3. FDA stated that its field staff spent nearly 600 hours to provide information to us, and headquarters also spent time to compile information and to respond to questions about the program. We had to collect follow-up information directly from staff because it was not readily available in FDA's FACTS data system or other electronic data systems. We specifically asked FDA not to create documents or compile data after the fact. While routine interviews are always involved to clarify our understanding of agency documents and data, this study was designed and intended to be primarily an analysis of FDA data on the program.

4. As we note in comment 1, we revised our second recommendation to address the need to minimize the overall time frame to protect cattle. Comments 11 and 13 discuss FDA's concerns with the other two recommendations.

5. FDA points out that it also has a feed testing program for imported feed and feed ingredients. Our report focused on the domestic feed testing program that FDA identified as a component of its BSE oversight during our earlier study, which resulted in the February 2005 report. We did not assess the import feed testing program.

6. We last examined USDA and other federal BSE detection and prevention efforts—other than FDA—in 2002 in a report entitled *Mad Cow Disease: Improvements in the Animal Feed Ban and Other Regulatory Areas Would Strengthen U.S. Prevention Efforts* (GAO-02-183; Jan. 25, 2002)

7. We agree with FDA that feed testing alone may not be able to verify the presence of prohibited material and that follow-up is necessary to determine whether the feed ban has been violated. Thoroughly documenting follow-up actions and the rationale for compliance determinations is critical to FDA's effective oversight of the feed ban. Our report recommends that FDA fully implement the 2005 directive and revised assignment that require its districts to thoroughly document the basis for their decisions.

8. FDA maintains that it is assessing the potential usefulness of feed testing. Because feed testing is using FDA's limited BSE oversight resources, it is imperative that FDA properly exercise oversight of the program by evaluating the costs and benefits, developing measurable goals, and periodically assessing trends to optimize the use of these resources. We believe that implementing our recommendations will help FDA in its assessment.

9. FDA describes the refinement of PCR technology in the context of an ongoing technology evaluation. FDA officials made similar comments during the course of our work. However, FDA did not provide any

information on the evaluation criteria it is using to measure performance or on the cost of developing and refining PCR technology.

10. The draft and the final report clearly state that the feed testing program is a small part of BSE's oversight effort and provides FDA with additional information about some sample feed.

11. We are continuing to include a recommendation that FDA fully implement the June 2005 directive and the July 2005 revised assignment to help ensure that FDA maintains its momentum and commitment to the new procedures. Because the feed testing program draws resources from FDA's BSE oversight activities, it is important that FDA avoid implementation weaknesses that limited the potential usefulness of testing under the 2003 assignment. In conjunction with our other recommendations, fully implementing the directive and the revised assignment will help FDA better assure the usefulness of the feed testing program as a tool in its BSE oversight efforts.

12. See discussion of the second recommendation in comment 1.

13. FDA disagreed with our assertion that the sampling assignment was poorly implemented and that it did not adequately oversee the program. According to FDA, the FACTS database was used to fully describe feed collection and laboratory activities and spreadsheets containing collection and laboratory information were distributed weekly and reviewed by FDA headquarters managers. FDA provided a copy of this spreadsheet that contained counts of the number of samples taken and the laboratory classification. However, each week's spreadsheet overrode the week before, and FDA's managers did not maintain previous versions. Furthermore, they could not provide any report that summarized their weekly review. Thus, FDA's managers could not do any comparative analysis, such as examining the type of feed sampled across districts. FDA also did not track or have any reports on follow-up activities or determinations to assess whether, for example, districts were using the same criteria. We envision a more substantive and meaningful oversight that might include comparisons of follow-up findings across districts, analyses of the number and types of new firms identified, assessments on how frequently follow-up involved only a file review or an on-site inspection, and decisions about what documents are consistently proving the most useful in expediting follow-up. These or other types of analyses give managers better information to assess program performance.

(360563)

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