Report on Food & Drug Administration Dallas District Investigation of Bovine Spongiform Encephalopathy Event in Texas 2005

Executive Summary:

On June 24, 2005, USDA informed FDA that a cow in Texas tested positive for Bovine Spongiform Encephalopathy (BSE). Information provided by APHIS was that the BSE positive cow was born and raised in a herd in Texas and was approximately 12 years old. The animal was sampled for BSE at a pet food plant in Texas on November 15, 2004, as part of USDA's enhanced surveillance program. The animal was disposed of by incineration and did not enter the human food or animal feed chains. Although the positive animal posed no risk to the animal feed supply, FDA, APHIS, the Texas Animal Health Commission (TAHC), and the Texas Feed and Fertilizer Control Service (TFFCS) conducted a feed investigation with two main objectives. The first objective was to identify all protein sources in the animal's feed history that could potentially have been the source of the BSE agent. The second objective was to verify that cattle leaving the herd after 1997 that were identified by USDA/APHIS as animals of concern (e.g. progeny and feed cohorts), were rendered at facilities in compliance with the regulation (21 CFR 589.2000) that prohibits most mammalian protein in feed for ruminants that became effective August 4, 1997 (herein called BSE/Ruminant Feed rule).

The feed history investigation identified 21 feed products that had been used on the farm since 1990. These feed products were purchased from three retail feed stores and had been manufactured at nine different feed mills. The investigators visited these establishments to collect information on formulations, shipping invoices, and use of ruminant meat and bone meal (MBM) on the premises both pre-1997 feed ban and post-1997 feed ban. This investigation found no feed products used on the farm since 1997 that had been formulated to contain prohibited mammalian protein.

The investigation identified one feed which contained an animal protein source that could not be identified. The investigation also found one feed mill that supplied feed to the farm that had used ruminant MBM in feed formulations for non-ruminant species after the BSE/Ruminant Feed rule went into effect, which is permitted under the rule, and that several feed mills had used ruminant MBM in feeds prior to the feed ban. Although the investigation did not identify a specific feed source as the likely cause of this animal's infection, it is probable that the most likely route of exposure for this animal was consumption of an animal feed containing mammalian protein prior to the implementation of the BSE/Ruminant Feed rule in 1997.

The investigation into the disposition of herd mates from this farm involved visits to nine slaughter plants and eight rendering plants. The investigation found that

all rendering plants were operating in compliance with the BSE/ruminant feed ban regulation. A review of the inspection history of each of these rendering firms found no violations.

Background of Investigation:

When notified on June 24, 2005, FDA Headquarters and Dallas District management officials immediately began making contacts with their Federal, State and Local counterparts to plan for and initiate follow-up investigational activities to determine the feed history in this herd and to assure the safety of the animal feed supply by evaluating current and historic compliance with the BSE/ruminant feed ban rule.

APHIS established a joint Incident Command Post and FDA Dallas District staffed this post full time with a Supervisory Investigator charged with coordinating activities between FDA, APHIS, TAHC and TFFCS. Coordination conference calls were set up with all Federal and State agencies involved in the investigation to keep everyone apprised of investigational developments.

Animal Tracing Activities and Renderer Follow-up Inspections:

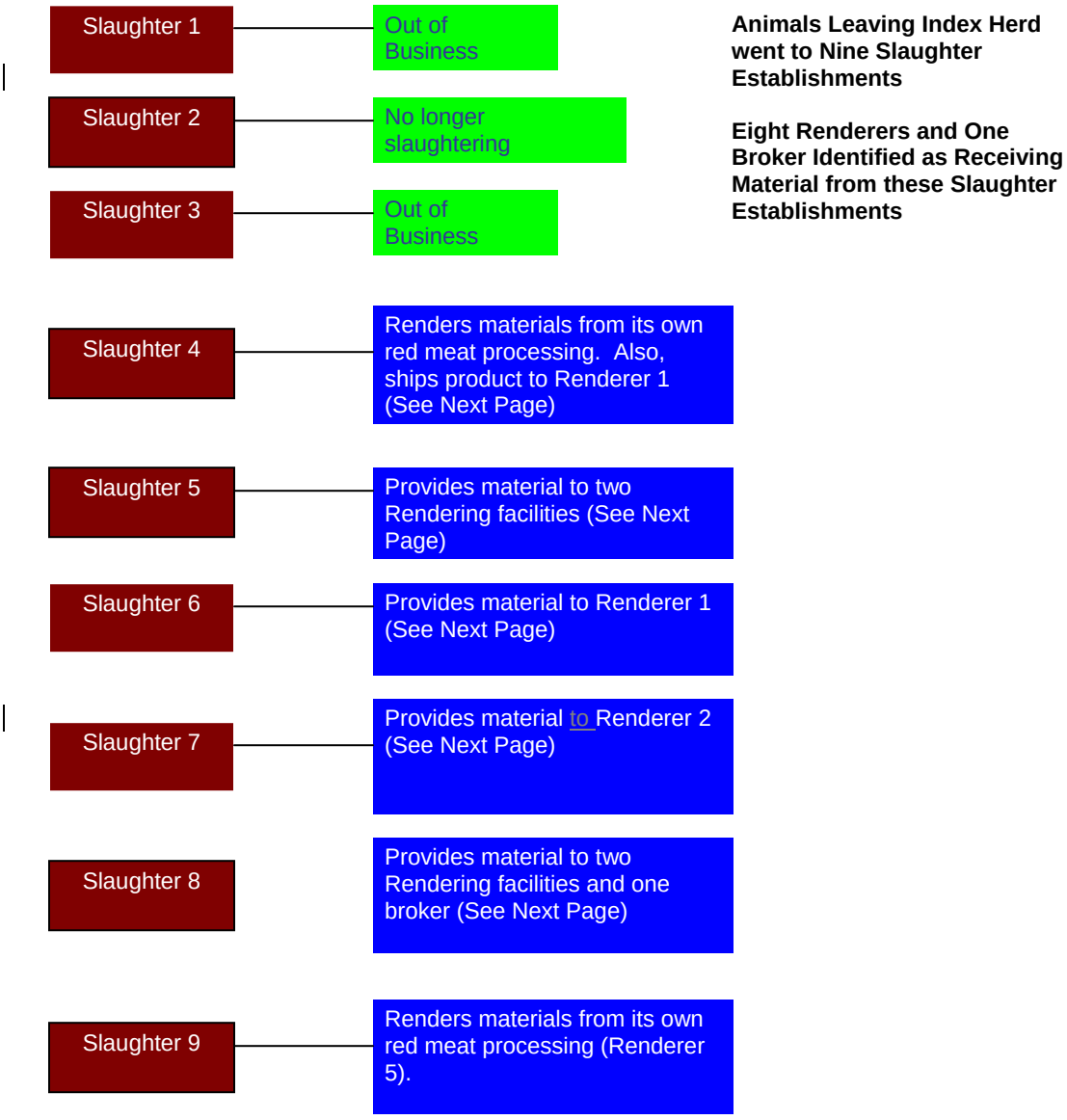
One of APHIS' primary objectives was to identify and trace the animals of interest (animals of interest would include any animals which could have been potential birth cohorts or feed cohorts of the index animal, or potential offspring of the index animal within the two years prior to the positive diagnosis) from the index herd. This objective included the identification of points of sale and ultimately the actual slaughter facilities for animals of interest that left the farm. As the trace information was developed, APHIS shared this information with FDA. Further information on animal of interest identification and tracing can be found in the USDA Texas BSE Final Epidemiology report.

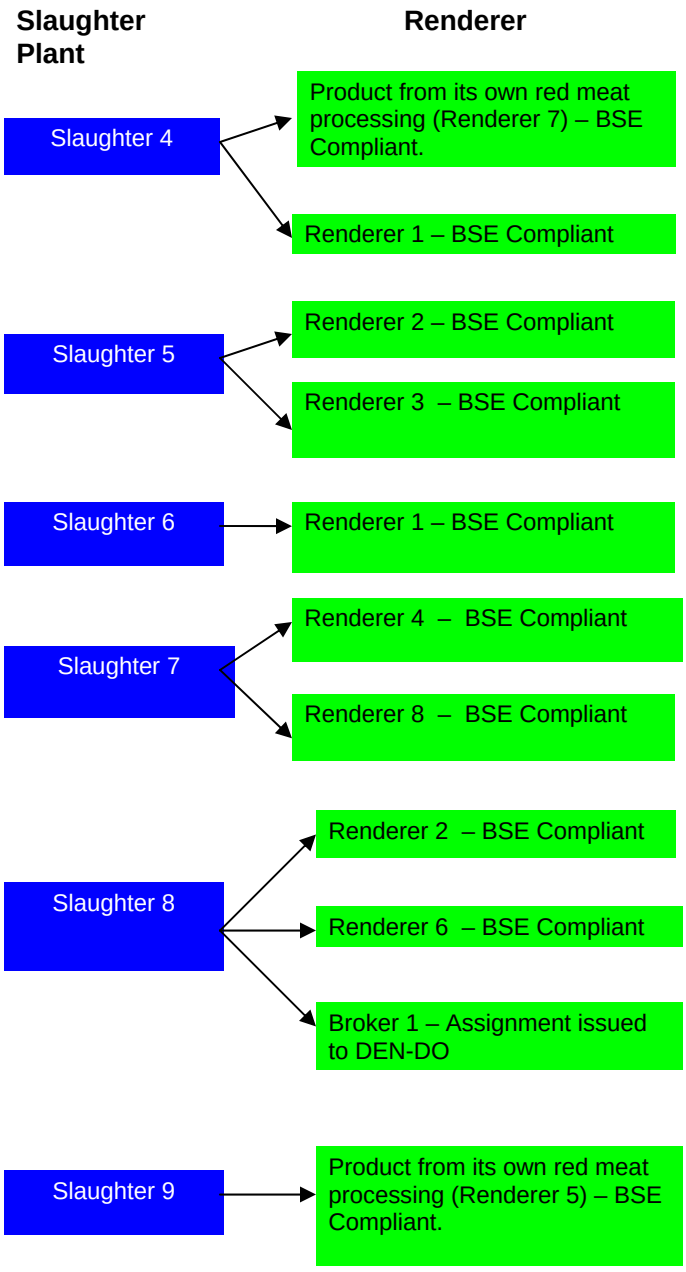
APHIS identified nine slaughter establishments receiving these animals of interest. Eight of the slaughter establishments were located in the State of Texas and one was located in the State of Georgia. Dallas District Investigators notified USDA/FSIS of our plans to visit each slaughter establishment to identify rendering facilities receiving materials from these slaughter establishments during the timeframe they received animals of interest. Dallas District also issued an assignment to Atlanta District to visit and inspect the one slaughter/renderer establishment located in the State of Georgia.

Eight renderers and one protein source broker were identified as receiving materials from these slaughter establishments. Each rendering facility identified was inspected for current compliance with the mammalian protein feed ban rule. Each firm's operations during the period of time of receipt of these animals post 1997 were evaluated from a historical viewpoint and no evidence of non-compliance was detected.

In all, FDA visited nine slaughter facilities, eight rendering facilities and one broker of these materials. All facilities inspected were found to be in compliance with the BSE/ruminant feed ban rule

Following is a graphical representation of the animal product follow-up work performed.





Results of Rendering Plant Inspections

All inspected renderers were BSE Compliant

Slaughter Plant

BSE Compliant

Feed Investigation:

As information was learned about the index herd, FDA Investigators working with TAHC officials conducted multiple interviews with the producer of the animal regarding possible feeds, feed sources, animal husbandry practices, and other events which may have changed normal feeding practices over the course of the index animal's life in the herd and any other information which may have been helpful in identifying the possible sources of feed for this animal and herd. FDA corroborated this information through interviews at the retail feed supply stores where the producer purchased feeds.

Follow-up at these retail feed supply stores identified 21 possible feed products the producer may have used during the history of the herd. Fifteen purchased feed products were identified, along with hay, native grass, rice straw, soybean meal, milk replacer/colostrum and bagged corn. These products were identified as originating from nine different manufacturers. Each of these manufacturers was inspected by FDA Dallas District and TFFCS Investigators.

Feed manufacturers were located throughout the State of Texas. An assignment was also issued to another FDA District to visit a Corporate Headquarters facility in an effort to review archived feed formulations and labels. During each of these inspections, the firm's current compliance with the BSE/ruminant feed ban rule was evaluated and attempts were made to determine the protein sources used in feeds on the index farm. Many of the feeds investigated were manufactured and used prior to the implementation of the BSE/ruminant feed ban rule in 1997. Feed products of particular interest included any which may have contained a protein source and the primary focus was on identifying any possible mammalian protein source material in those feed products. We found that ruminant feeds that had contained mammalian meat and bone meal (MBM) prior to the BSE/ruminant feed ban rule had been discontinued or reformulated upon the implementation of these rules. There is no regulatory requirement for a feed mill to archive formulations for that length of time, so in those instances where an actual formulation could not be obtained, experienced employees of the firms were interviewed and their recollections recorded.

Of all the feeds in use by the producer since 1997, none were discovered to have contained prohibited material (mammalian protein). Since the age of the index animal was determined to be approximately 12 years, investigating and reconstructing a feed history over such a long period of time is challenging. This ranch is a beef cow-calf operation and minimal feed records were maintained. Due to the nature of this investigation, it is difficult to determine what feeds were in use at specific times and what the formulation of those feeds were at the time they were fed. A feed history was developed through interviews with the producer and other farm personnel since they did not maintain any feed history documentation. Interviews with personnel at retail establishments disclosed incomplete records and cash sales that did not always identify the purchaser. Dallas District investigated any and all feed ingredients that were identified as being fed or potentially fed over the course of the last 15 years of this herd's

operation. Feeds discovered during this investigation with potential mammalian protein sources are as below:

- One feed, used prior to 1996, before the implementation of the feed ban, was suspected to contain mammalian meat and bone meal, but this could not be confirmed as no formulation records were available.

- The producer recalled using a particular feed sporadically during the 1980's and 1990's, however, he could not remember the name or manufacturer of the feed and had no records identifying the product. It is not known whether this feed contained an animal protein source. Attempts to identify this feed through interviews with retail sources were unsuccessful.

- The producer identified one feed product that has been used since the year 2000 which contains fish meal as a protein source. Further investigation revealed that this product had contained mammalian meat and bone meal prior to 1997, but that it had been reformulated at that time using fish meal to replace the MBM.

A tabular representation of the feed inspection follow-up activities is presented below:

Feed	**Dates of Use**	**Protein Source**	**Current BSE Inspection**	**BSE Compliance History**
Feed #1 - Range Meal	1980's - 2000	Unknown - Unable to determine actual manufacturer, no records available from producer	N/A	N/A
Feed #2 - High Protein Starter Feed	2001 to present	Feather meal	BSE Compliant	BSE Compliant
Feed #3 - High Protein Starter Feed	~1995 - 2001	Feather meal	BSE Compliant	BSE Compliant
Feed #4 - Cottonseed cake	Prior to 1990	Cottonseed meal	BSE Compliant	BSE Compliant
Feed #5 - Cottonseed cake	Early 1980's - 1990's	Cottonseed meal	BSE Compliant	BSE Compliant

Feed	Dates of Use	Protein Source	Current BSE Inspection	BSE Compliance History
Feed #6 - Limiter	2001 to present	Feather meal	BSE Compliant	BSE Compliant
Feed #7 - Creep pellets	Prior to 1970	Likely feather meal - no formulation could be obtained	N/A	N/A
Feed #8 - Lick tub	Since 2000	MBM prior to 1997 Fish Meal since 1997	BSE Compliant	BSE Compliant
Feed #9 - Cottonseed meal	Continuously	Cottonseed meal	BSE Compliant	BSE Compliant
Feed #10 - Range Cubes	Continuously since 1990	Feather meal	BSE Compliant	BSE Compliant[1]
Feed #11 - Sulfur Salt Block	Continuously	Minerals; calcium - all non-animal derived	BSE Compliant	BSE Compliant
Feed #12 - Lick tub	Continuously since 1995	Feather meal	BSE Compliant	BSE Compliant
Feed #13 - Beef Supplement	Prior to 1996	Prior to 1997, suspect MBM - Not able to confirm, no formulation available	BSE Compliant	Same manufacturer as Feed #10[1]
Feed #14 - Mineralized Salt	Continuously since 1998	Minerals; calcium - all non-animal derived	BSE Compliant	BSE Compliant
Feed #15 - Soybean meal	Since 2000, sparingly	Soybean meal	N/A	N/A
Feed #16 - Corn	Continuously	Corn	N/A	N/A
Feed #17 - Rice straw	1996, during dry year	Rice straw	N/A	N/A
Feed #18 - Hay	Continuously	Hay	N/A	N/A

Feed	Dates of Use	Protein Source	Current BSE Inspection	BSE Compliance History
Feed #19 - Milk Replacer	Since 2000, Infrequent use	Dehydrated colostrums, whey	N/A	N/A
Feed #20 - Grass	Continuously	Native grass	N/A	N/A
Feed #21 - Soybean meal	Since 2000, sparingly	Soybean meal	N/A	N/A

Dallas District previously documented one incident of the accidental addition of mammalian protein to a feed that was to be used for cattle at this facility. This incident was isolated to the manufacture of one lot of a custom cattle feed. A cross contamination error resulted in mammalian meat and bone meal being accidentally included in a feed. The error was detected soon after production. The firm acted swiftly in recalling the product and purchasing the animals that had consumed the feed. No products entered the human food or ruminant feed chain.

Dallas District Compliance History with BSE Feed Ban Rules:

Prior to 1997, feed manufacturers were not required to differentiate between protein sources used in ruminant and non-ruminant feeds. For a period of time following the implementation of the BSE/ruminant feed ban rule, some feed manufacturers continued to use both prohibited material and non-prohibited material within the same facility, employing separation and cleanout procedures to minimize cross-contamination. Although the regulations allow this practice, the potential for cross-contamination of ruminant feeds is greater. Most feed mills have found this practice to be difficult and have abandoned this practice.

Since the implementation of the BSE/ruminant feed ban rule in 1997, Dallas District and its State partners have inspected every known or registered feed manufacturer located in the states of Texas, Oklahoma and Arkansas. Further, every rendering operation and feed manufacturer actually processing with prohibited materials has been inspected annually. The compliance rate of the industry has been excellent.

Results:

In total FDA, along with TFFCS, conducted 33 inspections, investigations and interviews of the producer, retail feed establishments, feed manufacturers, corporate headquarters, slaughter facilities, renderers and a protein source broker. The FDA Dallas District follow-up to this incident resulted in the coordination of efforts of multiple Federal and State agencies. This report is the

physical output of many hours of research, planning and coordination. All of the inspections conducted confirmed the feed manufacturers and rendering operations to be in compliance with the current BSE/ruminant feed ban rule.

Dallas District conducts annual inspections of all feed mills and rendering facilities who handle, use or produce PM for feed use. Inspections performed since the initiation of the BSE/ruminant feed ban rules in 1997 have confirmed a high degree of industry wide compliance with these important safeguards. The district also routinely coordinates and shares information regarding feed inspections with the TFFCS who are also responsible for the evaluating feed ban compliance in the state of Texas.

Food and Drug Administration
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