Enforcement Strategy Update

FDA Regulation 21 CFR 589.2000

The BSE Feed Regulation

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A description of:

- *What we set out to accomplish when we implemented the regulation*
- *Progress during the regulation's first year*
- *How we plan to enforce the regulation during the coming year*
- *The resources we need to accomplish our compliance objectives*

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EDITOR'S NOTE: This List of Attachments was not included in the original document

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I. A Brief Summary of this Update

What We Set Out To Accomplish

- **FDA has placed a high priority on achieving compliance with the BSE feed regulation.**
  - That priority is equivalent to past and current agency initiatives involving known and immediate serious health consequences, and initiatives involving unquantified but potentially serious health consequences.
  - If bovine spongiform encephalopathy (BSE) were to occur in this country, the causative agent could be transmitted without detection and spread indiscriminately through the feeding of certain animal protein to cattle. This could result in an epidemic having a high cost in animal and even human lives, and economics.

> **PURPOSE OF THE REGULATION**
>
> Prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) by prohibiting the feeding of certain mammalian protein ("Prohibited materials") to ruminants.

- **Enforcing the regulation presents a unique, unprecedented challenge.**
  - BSE has not been detected in the United States. There are no practical tests to detect the presence of the causative agent during the preclinical stage, or to determine the species origin of protein products. Thus, enforcement generally has to be based on a paper trail, which provides opportunity for abuse.
  - In addition, the regulation reaches a number of diverse industries and subindustries including -- but certainly not limited to -- renderers, feed manufacturers and livestock

producers. Some of the regulated groups do not have experience in complying with the kind of regulation that the BSE feed regulation represents.

- **The FDA prepared an enforcement strategy that had the objective of 100% compliance by all regulated firms with all requirements of the regulation.**

  - We had the specific short term (two year) objectives of:

    - (1) *educating the regulated parties,* using our inspectional presence as appropriate, so as to achieve compliance if possible without resorting to enforcement actions, and

    - (2) *inspecting 100% of the regulated firms* (other than producers).

  - We described the strategy in a Draft Enforcement Strategy documents dated August 11, 1997. Among other guiding principles, we planned to

    - partner with the states and "piggyback" onto existing surveillance, sampling and enforcement programs to maximize efficiency, and

    - communicate regularly with the regulated industry to enhance compliance.

KEY STARTUP DATES

6/5/97	Final rule issued
8/4/97	Rule effective with certain exceptions
8/11/97	Draft Enforcement Strategy prepared
10/3/97	Rule fully effective
1/29/98	Assignment issued to FDA districts

First Year Accomplishments

- Reaching compliance objectives

  - We projected a 75% compliance rate on the first round of inspections

  - Actual compliance rates in FY 98 were:

    - 50 to 85% of the renderers and feed manufacturers were in compliance with all aspects of the regulation

    - Compliance by renderers and feed manufacturers with individual requirements of the regulation varied from 50% to nearly 100%

    - Approximately 95% of the producers did not have prohibited material at their facilities, although only about 25% were in compliance with the regulation's documentation requirements

- Reaching inspectional and educational objectives

  - FDA and state inspectors inspected approximately 2,615 firms during the fiscal year ending September 30, 1998. This included inspections of about 50% of all renderers, and 15% of all feed manufacturers.

  - Approximately 80% of the inspected firms were aware of the existence of the regulation. However, not all of the firms that were aware of the regulation were complying with it.

How We Plan to Enforce the Regulation During the Coming Year

- We will consider modifying the enforcement strategy in key areas, for example increasing follow up visits and reinspections. This would lead to targeted enforcement actions as a means of increasing compliance rates.

  - We will provide initial and follow up training for FDA and state inspectors, emphasizing

    - how to conduct inspections in a manner that ascertains compliance with the regulations, and

- completing the inspector's checklist so that all data obtained during the inspections can be used for data and trend analysis.

- We will initiate educational efforts targeted to specific groups, in addition to reevaluating our overall educational strategy.

- We expect to accomplish 8,400 inspections in FY 99, including 7,650 feed mill inspections.

- We will address specific significant enforcement issues raised during the first year.

Actual and projected data indicate that achieving the goal of inspecting 100% of all renderers and feed manufacturers during the first two years is feasible, contingent on funding for FY 2000.

Resource Needs

The resources we need to accomplish our compliance objectives

- FY 99

  - $750,000 for state contracts and partnerships, training and scientific literature review.

  - 17 FDA Field FTEs

- FY 2000

  - $100,000 for 2-year evaluation conference

  - 17 FDA Field FTE's

  - Additional needs based on recommendations from evaluation conference

II. What We Set Out to Accomplish When We Implemented the Regulation

The Regulation's Main Requirements are that firms:

- Label prohibited material with a cautionary statement: **"Do Not Feed to Cattle or Other Ruminants".**
- Keep records of incoming and outgoing prohibited material.
- If the firm separates prohibited from nonprohibited material, it must have a documented system to avoid commingling and cross-contamination.

COMPLIANCE OBJECTIVES

A. Our Compliance objectives ("outcomes")

- *100% compliance at all levels in all segments of the affected industries.*

  NOTE: Although the ultimate objective is 100% compliance, the Draft Enforcement Strategy estimated that we would find a compliance rate of 75% in the first round of inspections.

- *Actual compliance, not just compliance with the regulation's paperwork requirements.* That is, prohibited materials will in fact not be fed to ruminants.

ACCOMPLISHING THE COMPLIANCE OBJECTIVES

B. How We Planned to Accomplish the Compliance Objectives: Short Term (Two Year) Inspectional and Educational Objectives

IMPORTANT EXPLANATIONS:

- **"Short term"** is two years starting 1/29/98 -- the date we issued the BSE Feed Regulation Assignment to the FDA Field -- and ending 1/31/00. Thus, the short term period spans three fiscal years.
  - The short term period is to be a time of intense inspectional and educational effort.
  - We planned to reevaluate and make appropriate changes in the Enforcement Strategy at the end of the two year period.
- The enforcement strategy's two main thrusts -- inspection and education -- are intertwined. For example, the first inspection of a firm will ordinary be for educational purposes.

INSPECTIONS

"The enforcement commitment will be sufficient to provide a credible threat to all segments of the affected industries. This will include an extensive and visible regulatory presence, both federal and state."

Draft Enforcement Strategy August 11, 1997

1. Inspection Strategy

- We planned an intense inspectional effort that includes:
  - *Inspection of 100% of affected firms (except producers)*

    NOTE: "Affected firms" for 100% coverage, as intended in the Draft Enforcement Strategy, includes approximately 300 renderers and protein blenders, and an estimated 13,000 off-farm feed mills (licensed and unlicensed).
  - *Inspection of a sampling of producers[1] through:*
    - tracing of shipments from suppliers to producers, and

[1] This is a change from the Draft Enforcement Strategy, which provided for 1000 planned, random producer inspections. We implemented the change in the Assignment issued 1/29/98, which provided guidance for the number of tracings to producers.

■■ BSE regulation inspection add-ons to tissue residue follow-up inspections

- Tracing of shipments backward and forward in the distribution system. This would give the inspectional program a cross-cutting feature to better identify noncompliers.

- Follow up of noncompliers

■ Specific objectives for the inspections during the short term period were:

- educate key personnel in the inspected firms

- to the extent possible, achieve compliance among noncompliers without resorting to enforcement actions (referred to as "compliance achievements")

- take aggressive and visible enforcement actions in appropriate cases; and

- gather information upon which to base changes in the strategy.

■ FDA's Kansas City District planned a **Pilot Program** involving educational inspections of Nebraska renderers. The purpose of the pilot was to work in conjunction with the State of Nebraska to identify segments of the industry that might not be adhering to or understand the new regulation. If noncompliance is determined, the establishment will be educated and encouraged to properly implement the regulation. (Editor's Note: Attachment H)

EDUCATION

2. Education Strategy

■ We based our strategy on the belief that education is a key factor in achieving the compliance objectives

■ Our short term educational objectives were for FDA, in cooperation with industry stakeholders and state regulatory agencies, to conduct education programs that

- reach a *high percentage of the affected firms*, and
- are *effective* -- that is, they are understood and acted upon by the affected firms.

- We planned to conduct both *general educational initiatives* (those done outside the inspectional program) and *one-on-one education* (during inspections). The general initiatives would support the inspectional program; for example, educating firms prior to inspection minimizes the need for reinspection.

- FDA, states and industry are to have an ongoing dialogue concerning compliance with the regulations. This will help assure that educational initiatives are timely and tailored to meet identified needs.

III. Progress We Have Made in the First Year After the Regulation Went into Effect

KEY MILESTONE IN IMPLEMENTING THE REGULATION: CVM issued a comprehensive Assignment to the FDA Districts January 29, 1998. The Assignment:

- Asks FDA District Office to coordinate with states in their districts to develop an inventory of the affected firms; coordinate inspection of that inventory, providing support to states as needed; and select a limited number of firms for tracing inspections
- Identifies the National Coordinator for enforcement of the regulation, and asks each district to designate a BSE Coordinator
- Provides a guide for inspectors, and a checklist which is to be completed during inspections and sent to CVM

ACCOMPLISHING COMPLIANCE OBJECTIVES

A. Progress Toward Accomplishing the Compliance Objectives

1. Compliance with the regulation's requirements

We have gathered data about compliance rates from two major sources: the CVM Data Base, and the Kansas City District's Pilot program. We have also obtained feedback on industry perceptions of compliance from reports prepared under contract by the Eastern Research Group, and data on dairy farmers awareness of the regulation from FDA Regional Milk Specialists.

a. Data from the CVM Data Base

The CVM BSE Regulation Data Base:

- Collects and summarizes compliance information obtained from the Inspector's Checklist.
- Provides information -
  - on individual firm inspection and compliance, to avoid duplication and to assist in planning future inspections
  - on a composite basis, for all inspections, to evaluate the status of compliance with key parts of the regulation

- Approximately 40 to 50% of inspected firms handled prohibited material
- Overall compliance rates (firms with no violations) for FY 98 were:

  ■■ Renderers 85%

  ■■ Licensed feed mills 72%

  ■■ Unlicensed feed mills 48%

  ■■ Producers

- ✦ Prohibited material not used 94-96%

- ✦ Compliance with record keeping requirement 22-32%

- Compliance with major requirements for FY 98 were:

Renderers handling prohibited material

- ■■ Cautionary statement 82-85%

- ■■ Systems to prevent cross-contamination (26-35%)[2] 77-83%

- ■■ Records 97%

All feed mills handling prohibited material

- ■■ Cautionary statement 63%

- ■■ Systems to prevent cross-contamination (82%)[2] 67%

- ■■ Records 85-91%

Licensed feedmills handling prohibited material

- ■■ Cautionary statement 78%

- ■■ Systems to prevent cross-contamination (81%)[2] 76%

- ■■ Records 93-99%

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[2] % of firms handling prohibited material that are separators, e.g., 26-35% of the renderers handling prohibited material that separate prohibited and nonprohibited material

Unlicensed feedmills handling prohibited material

- ■■ Cautionary statement 53%
- ■■ Systems to prevent cross-contamination (81%)[2] 60%
- ■■ Records 79-85%

b. Data from the Kansas City Pilot (All firms)

- ■■ Cautionary statement 72%
- ■■ System to prevent cross-contamination 79%
- ■■ Records 93%

c. Information from the Eastern Research Group (ERG) Report (Attachment A)

The latest ERG Report, October, 1998, included the following points:

- We have not identified any systematic noncompliance with the core elements of the regulation. In the view of many of our contacts, FDA's enforcement presence is substantial.
- Most of our contacts are unable to observe how thoroughly feedmills and renderers are complying with the paperwork and documentation elements of the regulation. There is a probably a lower compliance rate with some of the less apparent aspects of the rule, such as the requirements to ensure safe separation of prohibited and non-prohibited proteins.
- Concerns about compliance difficulties or any other controversy regarding the regulation are minimal.

- Some feed mill operators initially underestimated the complications posed by spillage and occasional use of pet food "set asides" (off-specification material) in feeds

- Numerous feed mills continue to achieve compliance by avoiding any use of prohibited protein in their facility

- Dairy cattlemen appear to have switched to alternative feed formulations with relatively little complaint.

2. Actual compliance with the regulation

- This is a measure of whether prohibited material is *in fact* fed to ruminant animals, not just whether the regulation's paperwork requirements (labeling and recordkeeping) are in order.

- A few tracebacks and traceforwards have found prohibited material that did not bear the cautionary statement; the records did not indicate the presence of prohibited material.

B. Progress Toward Reaching the Short Term Inspectional and Educational Objectives

ACCOMPLISHING INSPECTIONAL OBJECTIVES

1. Progress in Implementing the Inspectional objectives

- Number of inspections - FY 98

Category	FDA	State	Total
Renderers	133	39	172
Feed mills-licensed	278	222	500

Feed mills-unlicensed	575	1017	1592
Producers	130	221	351
Totals	1116	1499	2615

Source: Compiled by the FDA National Coordinator from FDA program data (PODS) and reports from individual states

NOTES:

1.These data may not include all of the inspections conducted by states on their own initiative
2.The inspections are believed to consist mostly of first-time inspections, and not tracing or follow up (reinspection) visits
3.Most of the inspections were conducted after the Assignment issued 1/29/98
4.Feed Mills - unlicensed" includes a small number of firms other than feed mills, e.g. distributors and retailers

Efficiency in the Inspection Process

- 61% of medicated feed GMP inspections conducted during FY 98 had a BSE inspection "add on."
- 33% of tissue residue inspections conducted during FY 98 had a BSE inspection "add on."
- A significant percentage of state feed manufacturer inspections during FY 98 added BSE to the regular inspection. The state BSE-related activities ranged from basic educational efforts to regular inspection including completing the inspections checklist.

- Implementing the inspectional objectives -

  - presence-based education

    Inspectors provide on-the-spot advice, and copies of the Small Entity Compliance Guides (SECGs) and other educational materials to inspected parties. We believe that nearly 100% of the firms that need to comply with the regulation received copies of the SECGs.

  - compliance achievements

    Noncomplying firms were asked to make commitments to correct noncompliance. We do not

yet have data from follow up inspections to verify compliance. However, the general impression is that the corrections will in fact be made.

- enforcement actions

  We have not initiated any enforcement actions thus far. We intended the first round of inspection to be primarily for educational purposes. We were prepared to consider enforcement actions after first inspection only in egregious cases. We did not find any such cases in the first year.

- information gathering

  As described elsewhere, we are gathering information through the CVM Database, the Kansas City pilot program, FDA Regional Milk Specialists, and ERG studies.

ACCOMPLISHING EDUCATIONAL OBJECTIVES

2. Progress in implementing the educational objectives

- Measures of awareness

  - *Data Base*: Following data on awareness of the regulation prior to the first inspection:

    Overall - 80%

    Renderers - 87%

    Licensed feed mills - 92%

    Unlicensed feed mills - 85%

    Producers - 59-78%[3]

  - *Kansas City Pilot study*: Awareness of the regulation

[3] Includes data from Regional Milk Inspectors (See Attachment B)

Overall: 96%

Renderers: 100%

Licensed feedmills: 98%

Unlicensed feed mills: 99%

Ruminant feeders: 82%

- Measures of educational effectiveness

The data indicate that not all of those who are aware of the regulation are complying with it. However, we do not have data on noncompliance rates by those who have been exposed to a specific educational initiative (as distinguished from those who have mere knowledge of the existence of the regulation).

- What FDA and others are doing to implement the educational objectives

FDA, the states and regulated industries have undertaken a number of educational initiatives. A brief list of some of the educational initiative follows. Details are in Attachment C. Attachment D is a list of educational materials that we have prepared or have obtained from others.

General initiatives

- Preparation and distribution of Small Entity Compliance Guides (SECGs)
- Q&As on the CVM Home Page
- Educational materials prepared and distributed by Kansas City District in cooperation with states
- Presentations at numerous national, regional and state meetings

Initiatives targeted to particular industries

- Feed industry - satellite teleconference (June 1998)
- Rendering industry - workshop (July 1997)

- Producers
  - CVM UPDATE directed to producers
  - The CVM UPDATE and SECGs were distributed through state and FDA regional milk inspectors
  - USDA/CREES mailing of producer SECGS to dairy and beef nutritionists

State and industry initiatives

- Preparation and distribution of educational materials
- Presentations at national, regional and state meetings

CONSUMER OUTREACH

3. **Consumer outreach**

- Objectives
  - Keep consumer groups fully informed of the plans, progress and results from implementation of the Enforcement Strategy
  - Provide for consumer input into the development of strategy for implementing the regulation
  - Provide consumer groups with assurance that FDA and the states are implementing the regulation to the fullest extent possible
- Actions
  - Consumer briefing: With organizational assistance from the Office of Consumer Affairs, we conducted a briefing for representatives of eight consumer groups in April 1998. The FDA's Acting Associate Director for Consumer Affairs, and CVM's Director, hosted the meeting. We presented an overview of plans and progress in implementing the regulation. We have

attached a letter of commendation as Attachment E.

- Consumer participation in telecast: We invited consumer groups to view the feed industry telecast, and had participation from a consumer group representative who was in the studio audience.

SUPPORTING THE OBJECTIVES

4. Administrative/scientific actions to support the objectives

We have undertaken extensive administrative actions to support accomplishment of the objectives. Highlights are listed below. Details are in Attachment F.

- Assignment issued to FDA District Directors 1/29/98
- Training
  - National training (FDA and State) in Kansas City in September 1997, attended by representatives of all states and FDA districts.
  - Initial (state and regional) training of approximately 250 investigators in 25 states.
- Coordination
  - Industry stakeholders: Briefing for industry leaders October 1997 and frequent informal communication
  - State regulatory agencies: active participation by Association of American Feed Control Officials (AAFCO) in all significant BSE regulation activities; joint planning and training activities by FDA district and state personnel; etc.
  - National coordination by full-time National

Coordinator; designation of BSE coordinator in each district; and monthly coordination calls involving FDA and AAFCO personnel

- Coordination with USDA APHIS and FSIS; the Center Director briefed the Interagency Committee on Animal Production and Food Safety (Attachment G).

- Information gathering and analysis (This is described elsewhere, e.g., Database)

- Test validation. FDA is validating a test, developed in Italy, that allows identification of bovine protein DNA.

- Compilation of educational materials (see Attachment D,

IMPLEMENTATION IN THE COMING YEAR

IV. How We Plan to Implement the Regulation in the Coming Year

ENFORCEMENT STRATEGY

A. Enforcement Strategy

1. We will consider modifying the strategy to accelerate follow-up inspections. This may be desirable in view of the rates of noncompliance that we have seen. We will:

   a. consider targeted enforcement actions, i.e., make examples of egregious violations by using authorities provided by the Federal Food, Drug, and Cosmetic Act and other authorities; and

   b. prepare a guidance document to implement the modified strategy.

2. We will consider amending the regulation to provide greater enforcement capability, such as requiring firms to have safeguards against the sale of prohibited material for feeding to

ruminants.

3. We will evaluate the tracing approach to determine whether it needs to be modified.

4. We will develop appropriate strategies for inspecting the industry segments other than renderers, feed mills and producers, e.g. commercial haulers, downstream distributors and retailers, etc.

5. We will identify states most likely to fall short of the 100% inspection goal, and take steps to provide needed assistance to those states and the relevant FDA districts.

6. We will consider reassessing the risk of BSE occurring in the U.S.

INSPECTIONS

B. Inspections

We project inspections during FY 99 as follows:

Category	FDA	State	Total
Renderers	362	25	387
Feed mills	2067	4750	6817
Producers	459	1000	1459
Total	2888	5775	8663

NOTES:
1. Source of FDA data: Workplan Projections

2. State feed mill inspections: 3,250 under contract, 1,500 in partnership states

Efficiency in the Inspection Process - FY99

- State contracts:

  - Tissue residue: 100% of all inspections of ruminant producers will have BSE element

  - Medicated feed: 100% of all inspections of firms not previously inspected will have BSE element

EDUCATION

C. Educating the regulated industry

- Specific areas of attention will include:
  - Educating producers through the Cooperative Extension Service
  - Education targeted toward commercial haulers and retailers
  - General - we intend to evaluate the overall educational strategy, and make adjustments as appropriate.

CONSUMER OUTREACH

D. Consumer Outreach

We briefed the consumer groups again in November 1998

SPECIFIC ISSUES

E. Addressing specific issues raised during the first year:

- In addition to followup inspections and other actions described above, we will address specific issues as follows:
- Interpretation and application of the regulation
  - Can the regulation be enforced adequately if **collective terms** are used?

    Action planned: Look for documented problems; consider amending the regulation to limit use of collective terms

- To what extent should the regulation be enforced against **retail feed stores and other downstream "distributors"?**

  Action planned: guidance document

- How can we insure compliance by **commercial haulers** -- rail, truck, etc.?

  Action planned: further study; cooperative efforts with industry

- Are other important **niches** being overlooked - unconventional renderers, brokers, etc.? ("Niche" = industry segment involved in the distribution of prohibited material, other than a traditionally regulated renderer, feed mill or producer)

  Action planned: review data from inspections thus far

- Are we adequately regulating feed **imports**?

  Action planned:

  ■■ training for government personnel, and education for importers and others

  ■■ enhanced enforcement surveillance

- What is the **definition of "on farm mixer"?**

  Action taken: we published draft guidance in the Federal Register on September 25, 1998

  Action planned: Finalize the guidance document

- What actions should be taken if we document the **feeding of prohibited material to ruminants?**

Action planned: guidance document will be written

- Other issues

Contingency plan - we will consider developing a plan for amendment and enforcement of the regulation if BSE is discovered in the U.S.

SUPPORTING THE OBJECTIVES

F. Administrative support for actions

1. Training

- We will conduct refresher and first-time training for the FDA District and state inspectors
- The training will (1) emphasize how to conduct an effective inspection rather than merely completing the checklist, and (2) promote consistency in inspections from state to state and district to district
- We will explore using computer based training to accomplish the training

2. Coordination with industry: We conducted industry leader briefings in November 1998

3. Development of guidelines

- Kansas City District is working with the State of Iowa on a pilot program to develop generic SOPs for feed mills that separate prohibited and nonprohibited material, including clean out and flushing.
- We will develop guidelines for safeguards.

4. We will refine the baseline data for renderers and feed mills so that we will have a more accurate estimate of the inventories in those areas

5. We will consider revising the Inspector's Checklist to clarify some of the questions that are on the checklist

6. We will modify the Tissue Residue Program and the Medicated Feed Program to include a BSE "add on"

FY 2000 INSPECTIONS

Projected Inspections during FY 2000

Category	FDA	States	Total
Renderers	--	--	--
Feed Mills	2000	2450	4450
Producers	500	1000	1500

NOTE: 1,400 feed mill inspections under state contract, 1,050 in partnership states or voluntarily

Accumulated totals from start of inspection process: 300 renderers, 13,000 feed mill inspections

RESOURCE NEEDS

V. Resources: What We Need to Accomplish the Short Term Inspection and Education Objectives

For FY 99:

Funding for state contracts and partnerships (for inspections to be conducted in FY 00)	$500,000
Training and coordination meetings	200,000
Scientific literature search	50,000
Total	$750,000
FDA Field FTEs	17

For FY 00

Two-year evaluation conference	100,000
FDA Field FTES	17

Additional needs based on evaluation conference

Task Order No. 7
Contract No. 223-94-8031

Summary of Price Movements, Compliance Patterns, and Enforcement Issues for the Final Rule to Reduce the Risk of an Outbreak of Transmissible Spongiform Encephalopathies (TSEs) in the United States

Final Report - Update
October 27, 1998

Prepared for:
Economics Staff
Office of Planning and Evaluation
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20852

CONTENTS

1.0 INTRODUCTION

This report updates to September 1998 the market impacts of the U.S. Food and Drug Administration (FDA) regulation to prevent an outbreak of Transmissible Spongiform Encephalopathies (TSEs). FDA implemented the regulation on August 4, 1997. This report describes the price and market change and compliance patterns among the principal affected industries including renderers, feedmills, transporters of agricultural commodities, and ruminant cattle producers.

ERG gathered the data for this report from a number of interviews with personnel in the rendering, feed, and animal producing industries. Because most of the persons contacted were expressing their personal opinions and/or discussing potentially confidential matters, ERG has not quoted the individuals contributing to this report.

2.0 RECENT PRICE MOVEMENTS

Table 1 presents monthly prices for mixed species meat and bonemeal (MBM) and 48 percent soybean meal from June 1997 through September 1998. The data from this table are also presented in two figures:

Figure 1—the timeline for mixed species MBM and average 48 percent soybean meal prices

Figure 2—the price differential between mixed species MBM and 48 percent soybean meal

2.1 MBM Prices

- As of September 28, 1998, mixed species MBM was at essentially the same price (a $1 per ton price premium) as 48 percent soybean meal. Before the TSE issue arose, mixed species had historically sold at a premium to soybean meal of $5 to $45 per ton. Table 1 shows, however, that mixed species MBM sold at a discount to 48 percent soybean meal throughout early 1997 (prior to regulatory implementation) and into 1998 (the first 6 months after implementation). MBM's recent slight price improvement relative to 48 percent soybean meal might be due to exceptional soybean harvests.

  One rendering executive judged, based on the current price of substitute feed supplements, that MBM in the current market would likely be selling for $45 per ton above soybean meal were it not for the regulatory impact. Thus, he estimated that the regulation has reduced MBM prices by $45 per ton in the current conditions.

Table 1

Monthly Mixed Species MBM and Soybean Meal Prices per Ton
June 1997 through September 1998

	Mixed Species MBM 50 % Protein, Illinois	Soybean Meal 48% protein, Central Illinois, rail			Difference Between Mixed Species MBM and Soybean Meal Prices (a)
		Low	High	Average	
June 9, 1997	$280.00	$277.00	$285.00	$281.00	($1.00)
July 14, 1997	$280.00	$279.50	$287.50	$283.50	($3.50)
August 11, 1997	$267.50 (b)	$264.00	$272.00	$268.00	($0.50)
September 8, 1997	$275.00	$300.00	$309.00	$304.50	($29.50)
October 13, 1997	$280.00	$240.50	$250.50	$245.50	$34.50
November 10, 1997	$227.50 (b)	$242.00	$249.00	$245.50	($18.00)
December 8, 1997	$230.00	$237.50	$247.50	$242.50	($12.50)
January 12, 1998	$210.00	$197.50	$204.50	$201.00	$9.00
February 9, 1998	$160.00	$202.00	$204.00	$203.00	($43.00)
May 11, 1998	$165.00	$154.00	$160.00	$157.00	$8.00
June 9, 1998	$157.50 (b)	$161.00	$162.00	$161.50	($4.00)
July 14, 1998	$175.00	$175.00	$183.00	$179.00	($4.00)
August 11, 1998	$172.50 (b)	$144.50	$150.50	$147.50	$25.00
September 3, 1998	$147.50 (b)	$139.50	$145.50	$142.50	$5.00
September 28, 1998	$130.00	$124.00	$134.00	$129.00	$1.00

(a) The difference between the mixed species MBM price and the average soybean meal price.
(b) The Wall Street Journal reported a range of mixed species MBM prices for these days.
For the purposes of this table the midpoint is presented.

Source: Wall Street Journal, Daily Cash Prices, 1997 and 1998.

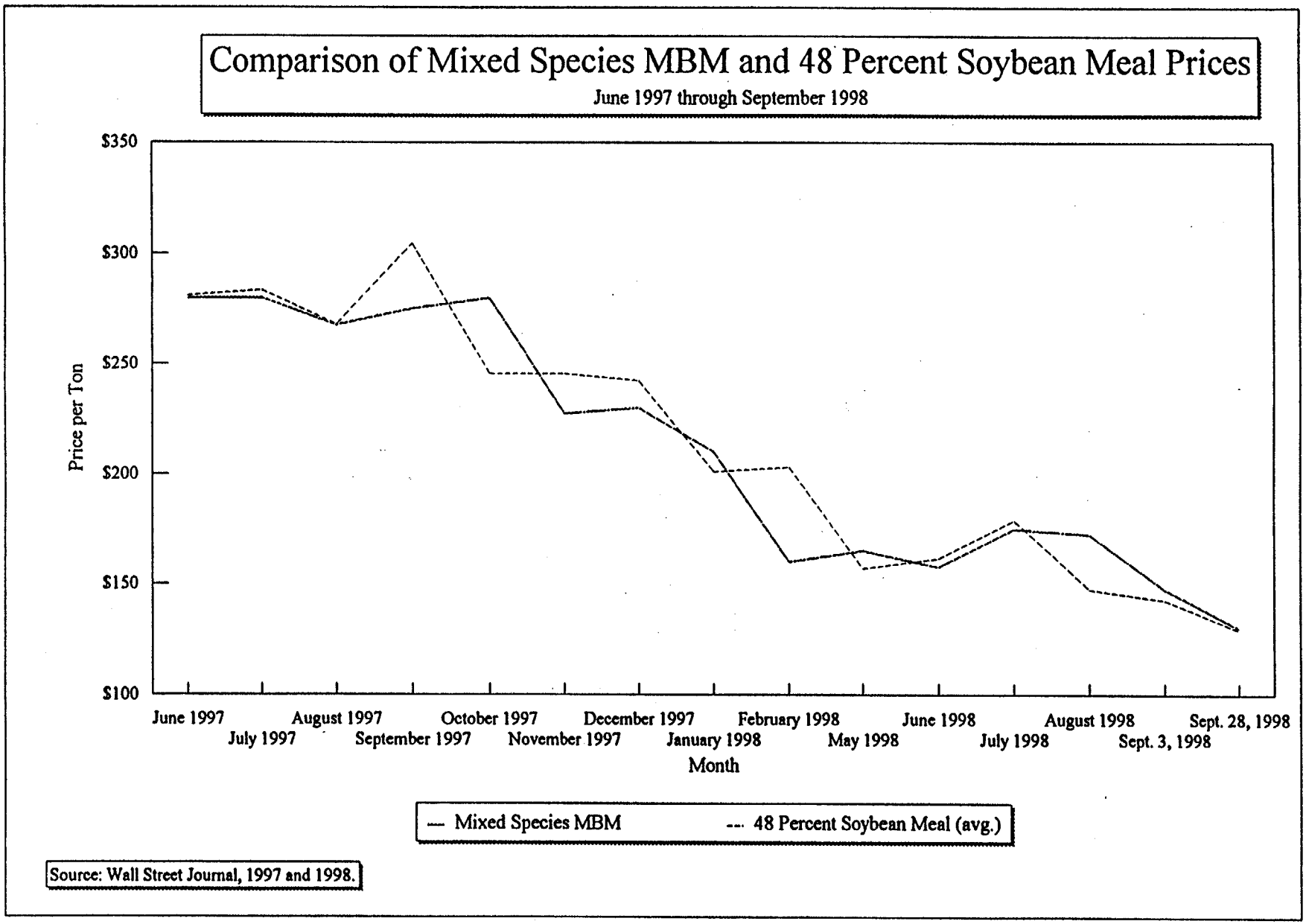

Comparison of Mixed Species MBM and 48 Percent Soybean Meal Prices
June 1997 through September 1998
$350
$300
$250
$200
$150
$100
Price per Ton
June 1997
July 1997
August 1997
September 1997
October 1997
November 1997
December 1997
January 1998
February 1998
May 1998
June 1998
July 1998
August 1998
Sept. 3, 1998
Sept. 28, 1998
Month
Mixed Species MBM
48 Percent Soybean Meal (avg.)
Source: Wall Street Journal, 1997 and 1998.

Figure 1

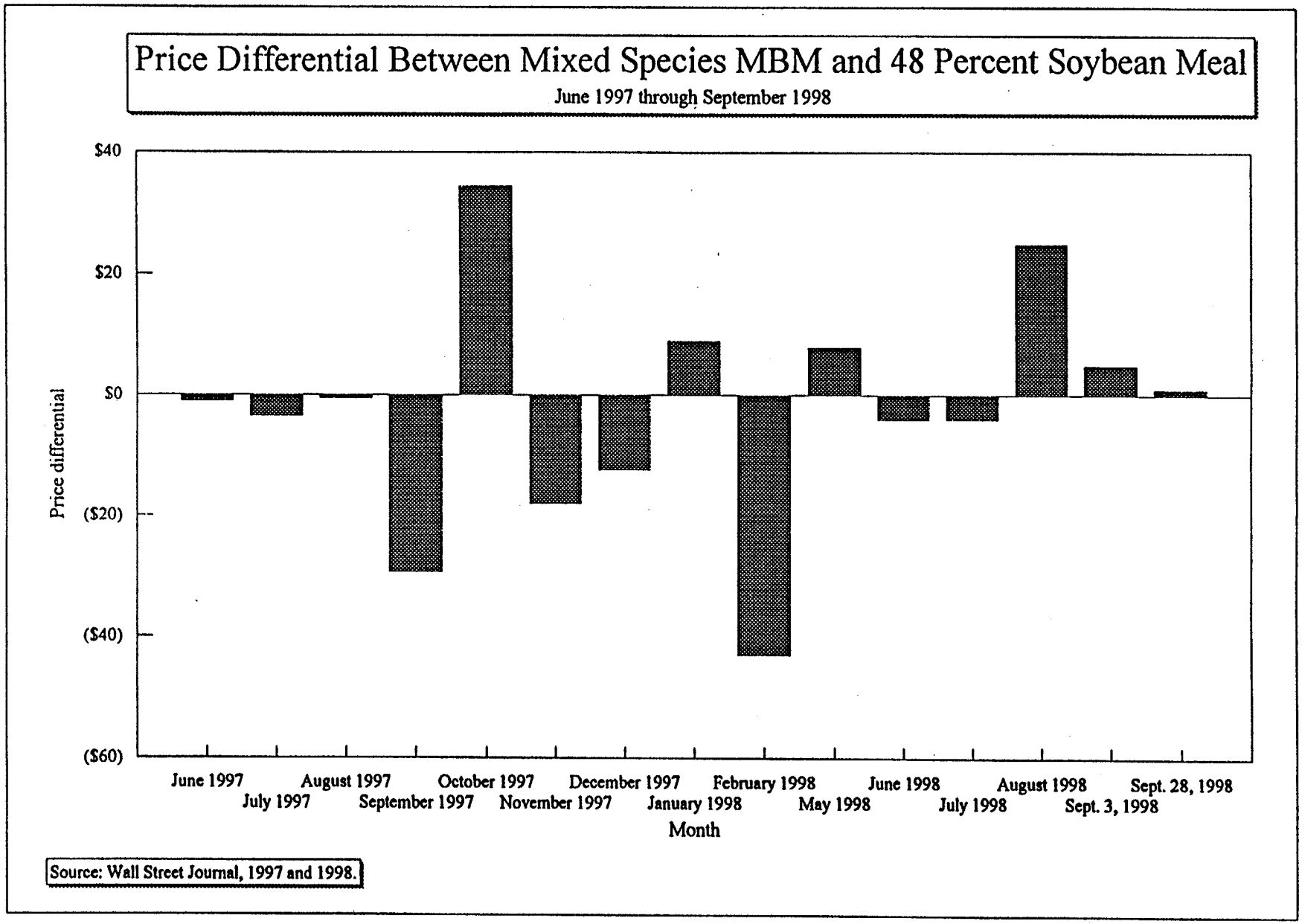

Price Differential Between Mixed Species MBM and 48 Percent Soybean Meal
June 1997 through September 1998
$40
$20
$0
($20)
($40)
($60)
Price differential
June 1997
July 1997
August 1997
September 1997
October 1997
November 1997
December 1997
January 1998
February 1998
May 1998
June 1998
July 1998
August 1998
Sept. 3, 1998
Sept. 28, 1998
Month
Source: Wall Street Journal, 1997 and 1998.

Figure 2

- The prices for mixed species MBM and 48 percent soybean meal have each fallen approximately $140 per ton since the FDA rule went into effect in August 1997. This large drop is part of a broad decline in the price of many agricultural commodities.

  Mixed species MBM price movements typically lag after those of 48 percent soybean meal, as shown in Table 1. For example, the price for 48 percent soybean meal fell sharply (approximately $40 per ton) between early December 1997 and early January 1998. Mixed species MBM prices fell an equivalent amount between early January 1998 and early February 1998. A similar sequence of price declines occurred starting in July 1998.

  For the MBM market specifically, the decline in the Asian market has also played a role in lowering MBM prices relative to other prices. Exports markets for MBM have been depressed since the beginning of the Asian financial crisis in 1997. Renderers had pursued these markets partly to replace the domestic customers lost because of the TSE regulation.

- Historically, pure porcine MBM (which is not restricted by the regulation) has sold at a premium to mixed species MBM due to its higher palatability in pet foods. This premium increased when the regulation was first implemented but has recently declined, at least temporarily. One large Midwest supplier is currently selling pure porcine MBM for only a slightly higher price per ton than mixed species MBM. In view of the higher protein content of porcine MBM, there is essentially no price premium per unit of protein. This current price relationship reflects partly recent high slaughter rates for hogs.

- Some feedmill operators have switched away from ruminant and mixed species MBM entirely, even though they are serving pork producers or other unregulated markets. These feedmill operators are avoiding mixed species or pure ruminant MBM because of concerns about the public perception of risk or to avoid the FDA compliance requirements associated with this rule.

  The decline in demand for mixed species and ruminant MBM beyond that mandated by the regulation suggests that the price decline for these products could have been much steeper. The essential substitutability of mixed species MBM and other proteins, however, limits the decline in price. For example, according to one major seller, mixed species and ruminant MBM at current market prices are now substantially more attractive for poultry rations than when these products held a significant price premium to 48 percent soybean meal. Poultry producers, therefore, are probably now consuming a larger share of overall MBM production than they did before the regulation was implemented.

2.2 Tallow and Hide Prices

- As of September 3, 1998, bleachable tallow is selling for approximately $0.17 per pound, which is $0.05 per pound lower than one year ago (Wall Street Journal, 1998). The European Union (EU) has been considering restrictions on tallow sales due to TSE concerns for some time, which might weaken tallow sales eventually. (Tallow is co-produced with MBM and is important to renderer profits. Domestically, the FDA's TSE regulation has probably had little direct influence on this market.)

- Hide prices have generally remained depressed since the beginning of the Asian economic decline in 1997. Exports previously accounted for 60 percent of U.S. hide industry sales.

2.3 Pickup Charges

- When the regulation was first implemented, some renderers increased charges for dead stock and supermarket pickups to offset lower tallow, hide, and MBM prices. The further decline in these prices during 1998 has increased the renderers need to increase pickup charges. Renderers have commented to ERG several times, however, that increasing pickup charges significantly reduces the amount of dead stock offered. Some farmers are willing to bury animals on their own land rather than pay increased pickup charges.

3.0 COMPLIANCE PATTERNS

3.1 Renderers

- The regulation requires renderers to label mixed species and pure ruminant MBM so that they are not fed to ruminant animals. Based on comments by industry observers and personnel contacted for this study, renderers are not knowingly selling these products for ruminant feed and are apparently in compliance with the TSE regulation.

- In the previous reviews of the regulatory impacts, ERG noted that renderers were often educating their customers about the TSE regulation. Among the contacts made for this study, one observer questioned whether renderers are always as proactive about educating potential customers as they might be. Given the high level of feedmill awareness and the labeling requirements, however, a very high percentage of customers, including virtually all feedmills, are probably aware of the regulatory restrictions. If material is sold to brokers, however, renderers might not

be extending themselves to monitor subsequent transactions for which they are not responsible.

- If any ruminant protein is being used for ruminant feeds, one observer suggested that such protein might be sold through commodity brokers. Brokerage sales are somewhat more difficult to track and a ruminant producer could occasionally purchase ruminant protein from several different brokers without becoming known to renderers or feedmill operators. Furthermore, brokers might be relatively unconcerned about FDA inspections. Nevertheless, ERG has no evidence that such sales are occurring.

- The FDA regulation requires renderers selling both restricted and unrestricted protein products to ensure that the two types of protein are separated throughout processing. Independent renderers, however, generally find it uneconomical to separate raw materials within their plants and, therefore, are not producing both restricted and unrestricted MBM at their plants. Thus the separation requirement of the regulation has had little effect on the rendering industry. ERG is not aware of any recent investments by renderers in new plant or equipment to allow separation of restricted and unrestricted protein products during 1998.

- The rendering industry is currently plagued with low profit margins and low returns on investment, which discourage investment in new plant and equipment, including investments to allow separation of proteins. The number of independent renderers in the industry continues to decline slowly.

3.2 Feed Manufacturers

- Awareness of the TSE regulation appears quite high. Some in the feed industry have been concerned that smaller feedmills (and some animal producers) still know very little about the regulation. Nevertheless, ERG did not identify any evidence that feedmill operators or their customers are behaving in a manner suggesting ignorance of the regulatory prohibitions.

  Most persons contacted felt that ample information had been made available to feedmills to facilitate their compliance. They commented that it remains the feedmill owner's responsibility to use the information provided.

- Based on our contacts, ERG did not identify any apparent non-compliance among feedmills with the core element of the TSE regulation, i.e., the prohibition on feeding of restricted protein to ruminant animals. In the view of many of our contacts, FDA's enforcement presence is substantial. For example, several people

judged it highly unlikely that a feedmill would risk FDA penalties (which they expected could include forced closure) by circumventing the regulation.

- Most of our contacts do not know how thoroughly feedmills and renderers are complying with the paperwork and documentation elements of the regulation. There might also be lower compliance with some aspects of the rule, such as the requirements to ensure safe separation of restricted and non-restricted proteins. Some feedmill operators have commented previously to ERG that they had originally underestimated the complications posed by spillage and occasional use of pet food "set asides" (off-specification material) in feeds. Additionally, one industry observer questioned how careful feedmills might be in preventing inadvertent contamination of raw materials (with ruminant protein) by transporters. (The transportation issue is addressed below). Some observers, however, judged that the feedmills they visited were attempting to operate "by the book."

- ERG again found that numerous feedmills are achieving compliance by avoiding any use of restricted protein in their facility, thereby simplifying their compliance requirements. We have found a number of feedmills that have eliminated restricted proteins even though they did not have any ruminant customers. For example, some feedmills in the Midwest serving only hog producers eliminated all restricted proteins from their mixes.

- There appears to be little resistance to compliance or controversies about the regulatory requirements among feedmill operators or their customers. For example, state feed and grain industry representatives report few complaints from or discussions with their membership about the regulation.

- As noted above, one large Midwestern supplier of porcine MBM is selling it for only a slightly higher price per ton than mixed species MBM. As a result, there is currently little price incentive to circumvent the regulation in that region. Thus feedmills are able to substitute pure porcine MBM for mixed species MBM without increasing prices for their customers.

- Persons contacted in the Northeast and in the Far West regions stated that a price incentive for non-compliance exists because mixed species MBM is generally cheaper than other animal-derived protein sources. Porcine MBM is not readily available in these regions. Vegetable protein is widely used but generally requires additional supplements to provide all of the nutrients found in MBM.

  A nutritionist operating in the Far West reported that most feedmills in the region eliminated restricted ruminant protein from all their mixes. Again, there is no indication of any noncompliance in ruminant animal feeding. Some feedmills

incorporated blood meal into cattle rations and the price for this product had increased substantially since the regulation went into effect.

A nutritionist in the Midwest commented that dairy farmers in his area were not using blood meal extensively as a substitute source of protein partly because they fear that it might eventually be found unsafe as a feed supplement. In this area, supplies of pure porcine MBM are ample to supply the demand for animal-derived protein.

- Data on the population of feedmills are quite limited and ERG's contacts could not estimate the number of feedmills separating protein products in their facilities. Based on the assumptions that (a) a minority of feedmills are located in agricultural areas where it is significantly advantageous to carry both restricted and unrestricted protein products, and (2) numerous feedmills have chosen to eliminate restricted proteins from all feed mixes, ERG estimates that 5 to 20 percent of feedmills are separating protein products in their facilities. Even this range, however, is highly speculative. This estimate is exclusive of small feed mixers and feed dealers, which are unlikely to be handling multiple types of MBM.

3.3 Feed Dealers

- In previous market studies of the TSE regulation, a few feedmill industry contacts reported that some small feed mixers and dealers might be out of compliance with the regulation mainly because they were unaware of its requirements. In the contacts made for this study, this concern persisted although information about the regulation is now more widely disseminated. ERG's contacts did not reveal noncompliance or ignorance of the regulation although the coverage of our information on this industry sector is limited.

- Past industry contacts felt that the smallest dealers might be uninformed if they do not belong to the national or state feed associations. Alternatively, they may be affiliated with a major feed manufacturer, such as Ralston-Purina or Agway and these companies have encouraged compliance among their dealers. Because of the volatile nature of the feed market, however, these larger feed companies have limited market power to compel compliance by their dealers. Some feed manufacturers have attempted to exert more control by requiring their dealers to sign agreements stipulating that they will comply with the TSE regulation. Nevertheless, the large feed manufacturers might not be able to compel perfect compliance throughout their network of dealers.

3.4 Transporters

Transporters could contaminate unrestricted feed products with restricted protein if their vehicles are not adequately cleaned. Normal transportation arrangements, however, probably limit the opportunity for such contamination.

Renderers generally ship their mixed species MBM products in specially designed hopper trucks. End-dump trucks or rail shipments are also sometimes used. Feed deliveries are often made using specially designed trucks with pneumatic delivery systems for transferring the feed into the farmers' storage bins.

The renderers' hopper trucks have a V-shaped bottom with a hatch that is opened once the truck is positioned over the storage pit at a feedmill. The MBM might flow immediately out of the truck when the hatch is opened. Often, however, the driver will climb on top of the truck and initiate the flow of material by pushing a stick through the material toward the hatch. The inside surface of the hopper truck is slick and the MBM will generally slide out, leaving little residue. To clean the truck, the driver (or other worker) will sweep out the truck bottom and/or use an air hose to remove residues.

The opportunities for contamination of unrestricted feeds are limited for the following reasons:

- Virtually all commodity producers have an expectation that their shipping company will provide a clean truck or rail car for their products. Specifically, feedmills generally will expect and require a clean truck before they will load feed intended for one of their customers. Drivers are often asked to sign forms verifying that the truck was cleaned prior to loading another commodity.

- A very large share of restricted protein is shipped to feedmills or other large customers in dedicated trucks operated by renderer company employees or contract trucking firms and these drivers are likely to be exposed to information on the regulatory requirements. Similarly, most bulk animal feed deliveries are made in dedicated feed trucks.

- Even many of the independent truck drivers that transport MBM occupy a somewhat specialized niche within the agricultural commodity trucking industry. Relatively few independent owner-operators operate the appropriate hopper trucks to carry restricted protein and are willing to transport this material. As such, the MBM drivers are relatively experienced and knowledgeable about truck cleanout requirements in general, even if they are not familiar with the TSE regulation in particular. One representative of the independent owner-operator truck driver industry estimated that perhaps 80 percent of drivers have some awareness of the regulation or of the basic nature of this or similar cleanout requirements.

The hopper trucks normally used to transport MBM generally are not appropriate for delivering bulk feeds to feedmill customers. The likelihood that a truck used to transport MBM would immediately be loaded with bulk feed for delivery to a ruminant producer appears to be relatively small although some of those contacted believed that it happens with some frequency. Similarly, many feedmill trucks have specialized characteristics that make it unlikely they will be used for hauling protein products.

- Under some arrangements, truck drivers are penalized if the weight of the material delivered is less than that indicated on shipping documents. A relatively small discrepancy in load weight might trigger such a penalty and drivers are thereby encouraged to clean out the truck thoroughly.

Overall, it remains a possibility that transporters of restricted protein products might contaminate other products through negligent cleaning practices or ignorance of the regulation. Nevertheless, the amount of restricted protein shipped in vehicles not directly controlled by renderers or feedmills is limited, and the two types of vehicles generally are not interchangeable in their functions. Further, normal shipping practice would suggest that most residue is removed from transport vehicles and containers before other products are loaded.

3.5 Dairy and Beef Farms

- ERG contacted a selection of dairy farmers and nutritionists to assess compliance with the regulation. In the Illinois area, ERG's contacts indicated that dairy cattle have shifted extensively from ruminant MBM to porcine MBM in their nutrition mixes. One dairy farmer stated that the farmers in his area have never complained about the regulation nor would they feel that noncompliance was worth the risk it represented. Similarly, a dairy cattle producers' discussion group on the Internet has relatively little mention of the TSE regulation. Furthermore, compliance was largely accomplished by the feedmills when they substituted pure porcine MBM for mixed species MBM in dairy cattle feed.

- Beef cattlemen contacted for the study made similar comments. Many feedmills in these areas have replaced mixed species MBM with the vegetable protein sources that are abundant locally. Thus most beef cattle producers have had little choice but to comply.

- Many dairy and beef cattlemen appear to support the regulation. A small percentage of those contacted were critical of the regulation, stating that there were no health risk to begin with and that FDA had simply weakened the commodity markets.

REFERENCES

Wall Street Journal. 1997 and 1998. Daily Cash Prices.

REGIONAL MILK INSPECTOR VISITS - BSE REGULATION

5/5/98

	FARMS VISITED	FARMERS ON SITE	AWARE OF REGS.	NOT AWARE
Virginia	28	10	10	0
West Virginia	13	2	2	0
California and Arizona	3	2	2	0

7/7/98

REGION	VISITS	FARMERS PRESENT	AWARE OF REGS.	NOT AWARE
Central - East *former* Mid Atlantic	92	20	13	7
Northeast	15	7	1	6
Central - West *former* Central	47	42	25	17

7/27/98

REGION	FARMS VISITED	FARMERS PRESENT	AWARE OF REGS.	NOT AWARE
NE	19	19	19	0
Central/East (*former* Mid Atlantic)	53	17	8	9
SW	16	12	2	10
PA	59	35	26	9

BSE INSPECTIONS CONDUCTED BY FDA REGIONAL MILK SPECIALISTS FOR JULY - SEPTEMBER 1998

REGION	# Farms visited	# Farms w/ producer present	# producers aware of the regulations		# producers not aware of the regulations		# not available during visit
	#	#	#	%[1]	#	%[2]	#
NORTHEAST	30	8	5	63%	3	38%	22
CENTRAL EAST (formally Mid-Atlantic)	197	111	88	79%	23	21%	86
CENTRAL WEST (formally Central)	164	91	37	41%	54	59%	73
SOUTHWEST	20	14	1	7%	13	93%	6
PACIFIC	44	27	18	67%	9	33%	17
TOTAL	455	251	149	59%	102	41%	204

[1] These are a percentage of those interviewed for the region.

[2] These are a percentage of those interviewed for the region.

EDUCATIONAL INITIATIVES

General Initiatives

o *Small Entity Compliance Guides (SECGs)*

- We issued separate user-friendly guides tailored to each of the major industry segments affected by the regulation (February 1998)

- We announced the publication of the guides with the CVM UPDATE, and made the guides available on the CVM Home page

o *Q&As*

-this document supplements the SECGs by answering questions raised after we published the SECGs

-we issued the Q&As in July 1998 on the Home Page, and announced their availability by CVM UPDATE

o *Assignment*

We distributed copies of the CVM Assignment to the Field, dated 1/29/98, to affected industry groups.

o *Nebraska Pilot Study*

Kansas City District's Customer Outreach Program Staff (COPS) worked in conjunction with the State of Nebraska to identify segments of the regulated industry that need education, and to followup with appropriate educational outreach.

o *Presentations*

Representatives of CVM and ORA have made numerous educational presentations, e.g. to the U.S. Animal Health Association, the AFIA Nutrition Conference, an Ohio meeting of regulators and industry, etc.

o *State and industry groups*

-State and industry groups have prepared and distributed additional educational materials. They have also presented information on the regulation at regional and state meetings.

Initiatives Targeted to Particular Industries

o *Feed industry*

We cosponsored a satellite teleconference with feed industry trade associations and the Association of American Feed Control Officials (AAFCO), in June 1998. There were 225 downlink sites in 34 states. The industry sponsors have distributed tapes of the broadcast. CVM posted on its Home Page a written summary of the broadcast, in addition to answers to questions asked but not answered during the teleconference.

o *Rendering industry*

CVM personnel participated in a day long workshop (July 1997) sponsored by the National Renderers Association, and attended by representatives of over 90% of the renderers in the country.

o *Producers*

We have placed special emphasis on educational initiatives directed toward producers, because we do not plan to inspect 100% of them. We have undertaken the following educational intiatives:

- We published a CVM UPDATE which summarizes the responsibilities of dairy and beef producers (February 1998)

- The UPDATE is being distributed to all dairy farmers through the state milk inspectors

- We are distributing the SECGs for producers to selected dairy farmers during farm visits by the FDA regional milk specialists (2000 copies)

- At our request, the USDA Cooperative Rsearch and Extension Education

Service mailed copies of the producer SECGs to dairy and beef nutritionists across the country (500 copies)

BSE DOCUMENT COLLECTION

MATERIALS ORIGINATED BY:

A. FDA/CVM
B. FDA DISTRICT OFFICES
C. STATES
D. INDUSTRY
E. PRESS
F. OTHER SOURCES

A. MATERIALS ORIGINATED BY FDA/CVM

1. FEDERAL REGISTER, June 5, 1997, 62 FR 30936, Final Rule, "Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed."

2. Guidance for Industry #60, Animal Proteins Prohibited From Animal Feed; Small Entity Compliance Guide, June 17, 1997.

3. "FDA Update on Bovine Spongiform Encephalopathy," by John Honstead, D.V.M., M.S., Presented at Kansas City, MO, September 29-30, 1997.

4. CVM UPDATE, October 9, 1997, "Deadline for Ruminant Feed Rule."

5. CVM UPDATE, January 22, 1998, "Information for Dairy and Beef Producers -- Protein Feed Rules."

6. FDA/State Coordinated Inspection Request, January 29, 1998.

7. FDA Guidance for Industry #67 -- Small Entities Compliance Guide for Renderers, February 1998.

8. FDA Guidance for Industry #68 -- Small Entities Compliance Guide for Protein Blenders, Feed Manufacturers, and Distributors, February 1998.

9. FDA Guidance for Industry #69 -- Small Entities Compliance Guide for Feeders of Ruminant Animals with On-Farm Feed Mixing Operations, February 1998.

10. FDA Guidance for Industry #70 -- Small Entities Compliance Guide for Feeders of Ruminant Animals Without On-Farm Feed Mixing Operations, February 1998.

11. Materials from FDA's Briefing for Consumer Organizations, March 4, 1998.

12. CVM UPDATE, March 26, 1998, "FDA GUIDANCE ON RUMINANT FEED RULES AVAILABLE."

13. Summary of the BSE Feed Regulation by D. Geyer, May 12, 1998.

14. CVM UPDATE, May 15, 1998, "SATELLITE TELECONFERENCE ON FEED RULES ANNOUNCED."

15. Video -- "BSE: Understanding the New Regulations for Animal Feed," June 24, 1998.

16. Guidance for Industry #76 -- "Questions and Answers, BSE Feed Regulation," July, 1998.

B. MATERIALS ORIGINATED BY FDA DISTRICT OFFICES

1. Four Booklets on BSE Prevention by Kansas City District Office:
   "What Feed Manufacturers Should Know"
   "What Renderers Should Know"
   "Regulatory Requirements"
   "What Feed Manufacturers Protein Blenders & Distributors Should Know"

2. "Just a reminder..." mailer from KAN-DO & Iowa Dept. Of Agric.

C. MATERIALS ORIGINATED BY STATES

1. "Ruminant Livestock Producers and the Mammalian Protein Feeding Ban," Undated,Virginia Department of Agriculture & Consumer Services.

2. "Important Notice -- Mammalian Protein Feeding Ban," Undated, Virginia Department of Agriculture & Consumer Services.

3. Memorandum dated July 3, 1997, from Hersh Pendell, Oregon Department of Agriculture, to Members of Feed Industry.

4. Memorandum dated October 22, 1997, from Herschel W. Pendell, Oregon Department of Agriculture, to Selected Registrants of Commercial Feeds.

5. "BSE PREVENTION GUIDELINES," Indiana State Chemist and Seed Commissioner, November 1997.

D. MATERIALS ORIGINATED BY INDUSTRY

1. Feed and Feeding Digest, National Grain and Feed Association, "FDA Prohibition on Feeding Mammalian Protein to Ruminants Takes Effect Aug. 4," June 19, 1997.

2. Memorandum from National Milk Producers Federation (NMPF) to General Managers and Board, Animal Disease Advisory Committee, July 17, 1997.

3. Memorandum and Guidance dated July 29, 1997, from Richard Sellers, American Feed Industry Association (AFIA), to AAFCO Representatives.

4. Letter dated November 20, 1997, from Richard Sellers, AFIA, to Association Executive, with attached Memo and Guidance; addressed to AFIA Member Companies, dated July 10, 1997.

5. SANITATION AND HYGIENE IN THE PRODUCTION OF RENDERED ANIMAL BY-PRODUCTS, Don A. Franco, DVM, MPH, 1997.

6. FDA's Ban on Feeding Certain Mammalian Proteins to Ruminant Animals -- A Compliance Guide for Commercial Feed Mills, by National Grain and Feed Association (NGFA), with cover note to Richard E. Geyer, dated February 2, 1998.

7. Memorandum dated June 24, 1997, from National Cattlemen's Beef Association (NCBA), to Executive Committee, NCBA Member Organizations, re: FDA-CVM Mammalian Protein Ban, with cover sheet to Dick Geyer dated March 4, 1998.

8. Continental Grain Company, "Food and Drug Administration (FDA) Mammalian Protein Ban," dated March 6, 1998.

9. "CJD, BSE, nvCJD Information," by National Cattlemen's Beef Association and the Cattlemen's Beef Board, March, 1998.

10. "BSE Satellite Telecast a Major Hit," AFIA Home Page, July 8, 1998.

E. MATERIALS ORIGINATED BY PRESS

1. "Save Those Animal Protein Feed Receipts," DAIRY TODAY, September 1997.

2. "Inspection Assignments Issued for Mammalian Ban," FEEDSTUFFS, February 9, 1998.

3. "Success of FDA Satellite Conference on Mammalian Protein Pleases AFIA, NGFA," Grainnet web site (www.grainnet.com), June 26, 1998.

4. "FDA Addresses Feed Industry's Concerns on Rule, RENDER, August 1998.

F. MATERIALS ORIGINATED BY OTHER SOURCES

1. USDA/APHIS Veterinary Services, "Bovine Spongiform Encephalopathy (BSE), August 20, 1997.

2. AVMA Online News Issue Brief, "Bovine Spongiform Encephalopathy (BSE) 1997 Update," September 1997.

Prepared by: K. Kandra, 11/5/98

ATTACHMENT E

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date: March 5, 1998

From: Deputy Commissioner for External Affairs, HF-24

Subject: Joint CVM and OCA Consumer Meeting on BSE

To: Stephen Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine, HFV-1

Steve,

I wanted to take this opportunity to commend you for your collaboration with the Office of Consumer Affairs (OCA) in convening a second successful meeting with national consumer leaders on bovine spongiform encephalopathy (BSE). This issue requires a proactive partnership with consumers and industry and CVM has been responsive and sensitive to the needs of both of these groups.

The feedback I have received from OCA has been very positive about this meeting and about your ongoing collaboration in general. As the Office of External Affairs continues to improve service to their outside constituents, we also aim to increase our collaboration with each Center in order to accomplish this mission. CVM has been a model for other Centers in how they do business with OCA and other OEA components.

Again, I commend you for a job well done and look forward to continued partnership with your Center.

Sharon

Sharon Smith Holston

cc Dr. Michael Friedman

Adminstrative Action to Support BSE Regulation Enforcement

Assignment

We issued the Assignment Memorandum to the FDA District Directors, with an inspector's guide and checklist, on 1/29/98. The Assignment sets out the inspectional goals from the Draft Enforcement Strategy; asks the districts to work together with the states to achieve the enforcement strategy's inspectional objectives; and provides guidelines for tracing shipments, among other things.

Training

o With administrative leadership and support from the Kansas City District's Customer Outreach Program Staff (COPS), we conducted a training session for representatives of all FDA districts and all states in Kansas City on September 29-30, 1997. Those who planned, organized and conducted the training session received an FDA Group Recognition Award for their efforts.

o CVM, COPS and several district offices have conducted followup training for over 250 investigators (state and federal) in approximately 25 states.

Coordination

o *Coordination with industry stakeholders*

- We briefed industry association leaders in October, 1997. CVM's Director hosted the meeting. The purpose was to discuss the FDA and states' inspectional and educational plans.

- We have taken special measures to information industry leaders of new CVM publications. For example, we provided them with copies of the Assignment, so that industry firms could prepare for inspections.

- We have frequent informal communications with industry leaders. These contacts provide for timely, two-way exchange of information and rapid response to emerging problems. For example, we notified industry leaders of findings that several renderers were not adequately labeling prohibited materials, and that some dairy producers were not

aware of the regulation. The industry leaders responded with timely and appropriate educational messages for their members

o *Coordination with states*

- AAFCO officials have participated in all significant enforcement strategy planning and implementation discussions; training sessions; CVM-organized meetings involving outside parties; and formulation of policies on issues that have surfaced.

- FDA personnel have presented briefings on BSE regulation implementation at AAFCO meetings

- FDA district and state personnel have conducted joint planning and training activities, have coordinated inspections, issued joint communications to regulated firms, etc.

- CVM personnel have discussed the BSE regulation with state officials in ORA 50-state conference calls

o *Coordination within FDA*

- the nationwide inspection aspects of the enforcement effort are being coordinate full time by Ricky Rodriguez, Compliance Officer, Dallas District

- Each FDA District has designated a BSE coordinator

- We organized an agency BSE feed regulation coordinating group which has monthly conference calls

- We initiated briefings on implementation and resource issues for the Acting Commissioner and the Director of ORA's Office of Regional Operations

- We briefed the FDA Inspection Branch and Compliance Branch Directors during their annual meeting in April 1998; met with several district offices to facilitate implementation; and participated in several "red phone" discussions on the regulation

o *Coordination with other government agencies*

- We have established points of contact in USDA APHIS and USDA FSIS, and we have regular communication with those agencies

- The CVM Director briefed

ANIMAL PROTEINS PROHIBITED IN ANIMAL FEED

FDA'S BSE Feed Regulation, 21 CFR 589.2000, June 1997

Purpose: Prevent the establishment and amplification of bovine spongiform encephalopathy (BSE) in the United States through animal feed and thereby minimize any risk to animals and humans.

Conceptual basis: Low probability of BSE occurring in the United States, but high risk if BSE does occur. BSE is a transmissible spongiform encephalopathy (TSE); TSEs are not detectable during incubation and are 100% fatal.

The regulation: Prohibits the feeding of mammalian protein (with exceptions) to ruminants. The regulation is designed to apply the minimum regulatory measures needed to achieve the regulatory objective. It requires a cautionary statement ("DO NOT FEED TO CATTLE OR OTHER RUMINANTS") on the label of prohibited products, and records of prohibited materials received and distributed. Firms that handle both prohibited and nonprohibited material must apply measures to avoid commingling or cross contamination of prohibited and nonprohibited materials. The rulemaking involved extensive participation by other government agencies (e.g. FSIS, APHIS), industry groups and the public.

Affected industries: Renderers, protein blenders, feed manufacturers, distributors, retailers, ruminant producers.

Enforcement of the regulation: Because there is currently no test for the prohibited product, enforcement is primarily by paper trail. Goals include maintaining a significant regulatory presence, and tracing product through the distribution system. State regulatory agencies are joining with FDA in the inspectional effort. Approximately 500 inspections had been conducted as of early April, 1998.

Educational outreach: Education is an essential part of implementation. Activities have included publication of Small Entity Compliance Guides; coordinated efforts with industry groups; distribution of materials to dairy producers; satellite telecast for feed industry planned for June 24, 1998; and a consumer briefing.

Additional information: Final rule 62 Federal Register 30936 (June 5, 1997); Small Entity Compliance Guides available through FDA Center for Veterinary Medicine (CVM) Home Page, www.cvm.fda.gov; CVM Contacts Dick Geyer (301) 827-6648 or Gloria Dunnavan (301) 594-1726)

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) PILOT STUDY REPORT

NEBRASKA RENDERERS

CONDUCTED BY

NEBRASKA DEPARTMENT OF AGRICULTURE
AND THE
U.S. FOOD AND DRUG ADMINISTRATION
KANSAS CITY DISTRICT OFFICE

August 28, 1998

TABLE OF CONTENTS

EXECUTIVE SUMMARY

In February 1998, the U.S. Food and Drug Administration Kansas City District (KAN-DO), and the Nebraska State Department of Agriculture (NDA) initiated a study of the rendering industry in Nebraska to determine whether it was complying with the new regulation to prevent bovine spongiform encephalopathy (BSE). Effected on August 4, 1997, the regulation is intended to prevent the occurrence of this neurological disease in cattle, which has also been implicated in Creutzfeldt-Jakob Disease (CJD) in humans. The study was funded by FDA's Center for Veterinary Medicine (CVM).

The Nebraska Department of Agriculture conducted inspections of the twenty rendering facilities in Nebraska. Information was gathered about their use of mammalian proteins in the manufacture of feed ingredients and educating plant personnel about the regulation.

Kansas City District reviewed and categorized the findings, according to a model that quantifies compliance. Kansas City created a flow chart to readily place the findings in a database. Findings showed all the firms were in compliance with the regulation with 13 firms achieving a perfect score of 100.

The industry's overall compliance rate as discovered by the pilot study was excellent. Despite the superior level of compliance the findings did reveal a common problem in the required cautionary labeling which was not always conspicuous. We also observed that only the first page of multi-sheet invoices, were stamped with the cautionary statement. The deficiencies were addressed in a letter to all the rendering facilities from the National Renderers Association.

The success of this pilot study is due to the expertise, cooperation, communication and hard work of all the professionals in NDA and FDA. This successful partnership between federal and state regulatory officials validates the utility of this initiative.

THE PILOT STUDY

OBJECTIVE

Kansas City District and the Nebraska State Department of Agriculture conducted a pilot study to measure how the rendering industry was complying with the BSE regulation.

The regulation prohibits the feeding of mammalian proteins to ruminants with certain exceptions, such as blood, milk, gelatin, protein from horses and pigs, and plate waste (inspected and processed meat products that have been cooked and offered for human

consumption). The regulation requires renderers, protein blenders, feed manufacturers, distributors, and haulers to place caution statements on labels for products that contain or may contain prohibited materials. It also requires the regulated industry to prevent commingling or cross-contamination of prohibited and non-prohibited materials, to maintain written clean-out procedures and to keep records to show products comply with the regulation.

The purpose of the KAN-DO/NDA pilot was to educate the industry about the regulations and determine the extent of compliance in the rendering industry with the new regulation. The objective of the study was to establish a baseline for compliance with the BSE regulation and identify patterns of non-compliance with the regulation. In addition, it sought to extrapolate the experiences with the Nebraska rendering industry to renderers throughout the U.S.

On February 12, 1998, KAN-DO and NDA agreed to establish a BSE pilot program. The goal was to determine by March 1, 1999, or earlier, the extent of compliance with the new regulation. On March 11-12, 1998, KAN-DO's Customer Outreach Program Staff (COPS) provided training for NDA inspectors in Lenexa, Kansas on the requirements of the regulation. Subsequently, NDA inspected 100% of the rendering industry, applied the regulation and completed the BSE Checklist designed by CVM (questions 1-10) and modified for renderers (questions 11-16) by KAN-DO.

NDA furnished KAN-DO with the inspection reports and the BSE checklist. The information was developed into a database and used to identify industry compliance rates and any patterns of non-compliance.

ANALYSIS

A flow diagram was created for this pilot study to measure compliance rates in several different dimensions. The flow diagram was based on the CVM Checklist and had 100 possible points. Points were allocated for each regulatory requirement depending on the importance of the activity. Points were deducted for each non-compliant activity.

Individual firms were measured for compliance using the flow diagram (attachment A). The rate of the BSE compliance was calculated for all eighteen renderers (excluding the hog renderers). The average score was 95 points. Thirteen firms scored 100 possible points for complying with the BSE regulation.

Eight renderers handled both prohibited and non-prohibited materials, and had clean out processes and procedures to avoid commingling and cross contamination. The procedures varied from flushing with 500 pounds of non-prohibited materials which is then added to prohibited material; segregating non-prohibited materials from prohibited materials; and completely separating the processes of collection, manufacturing, and load out.

Sixteen renderers used the caution statement on invoices or bills of lading. Two renderers had point deductions for not having a conspicuous caution statement on invoices; one because the caution statement was not highlighted or easily noticeable by the purchaser; the other merely

wrote the caution statement in black ink on the invoice. Three renderers had no caution statement at all.

Two firms had no safeguards in place to prevent shipment of prohibited material to ruminants. They scored the lowest number of points, 75 because they did not use the caution statement or have safeguards in place to prevent outgoing prohibited materials from shipment to ruminant feeders. One renderer refused to sell prohibited material because there was strong evidence the customer was feeding prohibited material to cattle.

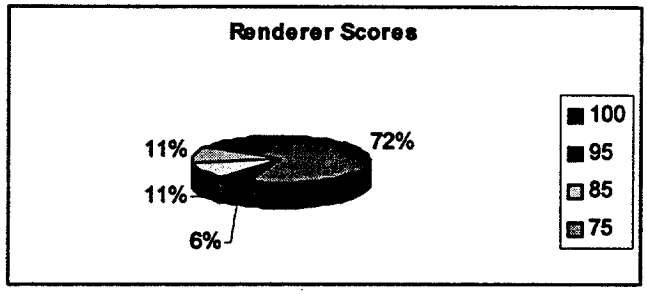
FINDINGS

All twenty renderers were inspected in Nebraska at an average of one and one-half hours per inspection, including completion of the modified checklist. Two renderers handled only pork protein, and were not included in the tabulations.

Two major findings came from these inspections. 1. Cautionary statement labeling was not conspicuous. 2. Only the first page of multi-sheet invoices, were stamped/labeled with the cautionary statement. These findings were discussed with the National Renderers Association (NRA) and a letter went out from their director to all of the NRA members addressing these issues.

Of the eighteen firms handling prohibited materials, thirteen (72%) scored the maximum 100 points using the model measuring tool. The remaining six scores ranged from 75 to 95 points.

The chart illustrates the points and percentages for all 18 renderers.



The table below tabulates the checklist responses for questions 2 through 10. (Question 4 was omitted because the responses were narrative.)

Question	*2*	*3*	*5*	*6*	*7*	*8*	*9*	*10*
Yes	20	18	15	18	8	7	16	2
No	0	2	3	0	10	1	2	0
Total	20	20	18	18	18	8	18	2

Below, the responses to the modified checklist questions 11 - 16 are summarized.

The most commonly produced products were:

- Dry rendered tankage
- Bleachable talo

- Greases
- Hides
- Lamb and chicken meal
- Meat and bone meal
- Pork meat and bone meal
- Blood meal
- Gel bones

Three renderers received imported protein:
- Lamb from Australia and New Zealand
- Cattle (offal) from Canada
- Horses from Canada

Ten renderers extracted products intended for non-human use, such as small intestines, hearts, livers, pituitaries, guts, bones, and pancreas, and adrenal and other glands.

Rendered products are shipped to the following sub-industries:

- Other renderers: 2
- Protein Blenders: 11
- Feed Mills: 11
- Brokers: 6
- Pet Food Manufacturers: 6
- Others: 3 (Chicken and gelatin producers, soap and film industry)

CONCERNS

During a joint meeting between NDA and KAN-DO regarding the pilot, various concerns surfaced. First, the jobbers (individuals who buy and take possession of animal by-products with the intention of selling for a profit) operate without invoices and are difficult to identify. They sell to anyone, including the ruminant feeders. When there is no proper caution statement on the product, it may be unknowingly fed to ruminants.

Second, the trucks used to ship finished meat and bone meal may not be cleaned, and the independent truck drivers are unlikely to review labels/invoices. This may result in cross contamination with the prohibited materials.

Third, it was discovered that firms under federal inspection, United States Department of Agriculture (USDA) were not getting inspected on the rendering side.

Finally, acceptable clean out processes and procedures should be defined for uniform and consistent operations among the renderers.

CONCLUSION

The new regulation to prevent the occurrence of BSE in U.S. cattle was effective among the rendering industry in Nebraska. The average compliance rate of 95 percent probably reflects the compliance of most rendering plants in the United States. Further study is needed to determine compliance rates for other industries, such as commercial feed mills, distributors and producers.

Continuous intensive efforts are needed to prevent the occurrence and spread of BSE. KAN-DO will continue cooperative efforts with its states, associations, industries, and consumer partners to achieve this goal.

ATTACHMENTS

A. Flow Diagram
B. Modified CVM Checklist
C. Letter from National Renderers Association

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