Bovine Spongiform Encephalopathy (BSE)

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Bovine Spongiform Encephalopathy (BSE)

Bovine Spongiform Encephalopathy (BSE), commonly called "mad cow disease", has had a substantial impact on the livestock industry in the United Kingdom (UK) and other countries where the disease has been diagnosed.

Through November 2006, the Office of International des Epizooties (OIE), the world organization for animal health, has reported there have been more than 190,000 cases of BSE documented in more than 25 countries since the disease was first diagnosed in 1986 in the UK.

Bovine Spongiform Encephalopathy (BSE)

There is also strong scientific evidence and general agreement that the UK outbreak was amplified by practices that involved the feeding of animal protein products derived from infected cattle to other cattle, especially young calves.

Infected carcasses and slaughter by-products were sent to rendering facilities where the material was cooked and processed into a powdered, protein-containing meat-and-bone meal (MBM).

This infected MBM was then incorporated as an ingredient into cattle feed. In 1988, the UK banned the use of sheep and cattle remains in cattle & sheep feeds.

United States Department of Agriculture (USDA) & Health and Human Services (HHS) Firewalls

- **The existing multiple firewalls, developed by both the USDA and HHS, Food and Drug Administration (FDA) have been extremely effective in protecting the American consumer from exposure to BSE.**
- **The firewalls include USDA and FDA import regulations, restrictions, and controls; USDA surveillance of the United States cattle population; and FDA's 1997 and 2008 animal feed ban regulations.**

BSE Import Regulations and Controls

- **The United States has implemented a number of measures since 1989 to prevent amplification of the disease in the United States.**
- **1989 – USDA, Animal and Plant Health Inspection Service (APHIS) prohibited the importation of live cattle and other ruminants and certain ruminant products, including most rendered protein products, into the United States from countries where BSE is known to exist.**
- **1991 - USDA banned imports of ruminant meat and edible products and most by-products of ruminant origin from countries with confirmed BSE cases.**

BSE Import Regulations and Controls

- **1997 - APHIS extended import restrictions on ruminants and ruminant products from all of the countries in Europe due to concerns about widespread risk factors and inadequate surveillance for BSE in those countries.**
- **2000 - APHIS expanded its prohibitions on imports of rendered ruminant protein products from BSE-restricted regions to include rendered protein products of any animal species because of concern that cattle feed supposedly free of ruminant protein may have been cross contaminated with the BSE agent.**
- **2000 - FDA issued import alerts on animal feed ingredients for APHIS-listed countries.**

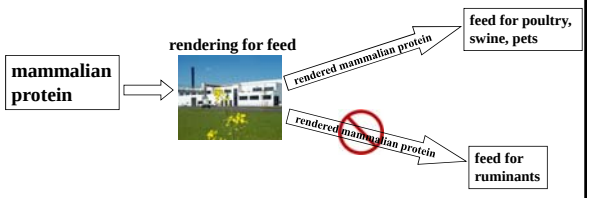
BSE Surveillance Program

- **1990 - The United States implemented an active surveillance program for BSE. The sampling strategy was designed to detect one BSE-infected animal per million cattle and to take into account regional differences while striving for uniform surveillance throughout the country.**
- **Since 1993, BSE surveillance in the United States has met or exceeded international standards as outlined in the Terrestrial Animal Health Code of OIE, the world organization for animal health.**

FDA Animal Feed Ban Regulations

- **1997 – FDA prohibited the feeding of all mammalian protein to cattle and other ruminants, with the exception of milk and milk products, blood and blood products, gelatin, plate waste, and pure pork and pure equine protein from single species processing plants (62 FR 30936; June 5, 1997; codified at 21 CFR 589.2000).**
- **Requirements:**
  - Adequate measures for preventing cross-contamination
  - Maintaining receipt, processing and distribution records for one year (and make available for inspection)
  - Labeling products with the caution statement "Do not feed to cattle or other ruminants"

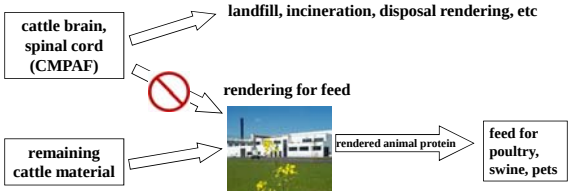
1997 BSE Feed Rule (Feed Ban)



FDA Animal Feed Ban Regulations

- **2008 – FDA prohibited the use of cattle material prohibited in animal feed (CMPAF) in ALL animal feeds (April 25, 2008; codified at 21 CFR 589.2001).**
- **Prohibits for use in ALL animal feed the following material known as "cattle material prohibited in animal feed" (CMPAF):**
  - brains and spinal cords from cattle ≥ 30 mos. of age
  - entire carcass of cattle not insp. & passed for human consumption
    - unless shown to be less than 30 months of age OR
    - brain and spinal cord removed
  - entire carcass of BSE-positive cattle, including tallow, defined as fat originating from cattle or bison (buffalo)
  - tallow made from CMPAF that contains more than 0.15% insoluble impurities
  - mechanically separated beef made from CMPAF

2008 BSE Feed Rule (Feed Ban)



FDA Animal Feed Ban Regulations

- **These two feed ban regulations, 589.2000 and 589.2001 were critical safeguards to help prevent the spread of BSE through cattle herds by prohibiting the feeding of most mammalian protein to ruminant animals, including cattle, and prohibiting the feeding of CMPAF to ALL animals.**

Results of Prohibited Mammalian Protein Regulations

The FDA's December 1998 enforcement plan for the ruminant feed ban rule includes education as well as inspections. Over 76,000 inspections have been performed as of March 6, 2010. The majority of these inspections (around 72%) were conducted by State feed control officials, with the remainder conducted by FDA officials.

Of the 8,885 firms handling prohibited material, their most recent inspection concluded that:

1 firm (0.01) was classified as OAI

192 firms (2.2%) were classified as VAI

Inspection Conclusions

- Inspection conclusions are reported as Official Action Indicated (OAI), Voluntary Action Indicated (VAI), or No Action Indicated (NAI).
- An OAI inspection classification occurs when significant objectionable conditions or practices were found and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified as OAI will be promptly re-inspected following the regulatory sanctions, in order to determine whether adequate corrective actions have been implemented.

Results of Prohibited Mammalian Protein Regulations

- A VAI inspection classification occurs when objectionable conditions or practices were found that do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified as VAI usually occur as a result of more technical violations of the Ruminant Feed Ban. Examples could include things such as minor recordkeeping lapses and conditions involving non-ruminant feeds.
- An NAI inspection classification occurs when no objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify any further actions on the part of the firm.

Regulatory Components and Administrative Strategies

- Enforcement
- Charges and Enforcement Approach
- Recalls
- Refusals

Enforcement

- Much of the industry has complied with the regulations as a result of education and voluntary compliance. However, some inspections still occasionally reveal that some firms are out of compliance. Whenever potentially violative conditions are found, evidence should be collected to support the enforcement action. Some of the primary tools for documenting violations would include inspectional observations, admissions, photographs, and record review.
- Warning letters should be considered for situations that are classified as OAI.

Charges and Enforcement Approach

- Adulteration – Section 402(a)(2)(C) of the Food, Drug, and Cosmetic Act prohibits the use of unapproved food additives. Section 402(a)(4) prohibits the use of material considered potentially injurious to ruminant and public health. Prohibited animal proteins in animal feeds and feed ingredients would cause the feed to be adulterated.
- Misbranded – Section 403(a)(1) of the Food, Drug, and Cosmetic Act prohibits a label to be false and misleading. Section 403(f) require any word, statement, or other information required to be displayed in a prominent or conspicuous manner. Animal feeds and feed ingredients that contain prohibited material but fail to bear the required caution statement or do not display it in a prominent or conspicuous manner would cause the feed to be misbranded.

Recalls

- When violations are encountered during an inspection, the firm's intentions concerning the recall of any adulterated and/or misbranded products from commercial distribution should be determined.
- The firm should be provided the opportunity to voluntarily recall all violative feeds and feed ingredients and dispose of the products appropriately.
- If the recall is ineffective or the firm refuses to voluntarily recall the product(s), State regulatory actions such as embargos or stop-sales should be initiated, along with an FDA-requested recall and press release.

Refusals

- Sections 703 and/or 704 of the Food, Drug, and Cosmetic Act provide that records of interstate movement of food and the holding thereof during and after such movement must be made available for inspection and copying.
- Refusal by a firm to access and/or copy such records will result in the FDA/Office of Enforcement (OE) consideration to obtain an inspection warrant under Section 704.

Texas Regulatory Program

- The Office of the Texas State Chemist (OTSC), Feed and Fertilizer Control Service (FFCS), under the direction of the Director of the Texas Agricultural Experiment Station is responsible for administering enforcement of the Texas Commercial Feed Control Act.
- Surveillance inspections are conducted under state and federal authority, to determine compliance with the FDA 1997 and 2008 feed ban regulations.
- Surveillance samples of animal feeds and feed ingredients are collected and analyzed under state and federal authority to determine compliance with the FDA 1997 and 2008 feed ban regulations.

Surveillance Inspections

- Approximately 500 surveillance inspections are conducted annually by the Texas Feed and Fertilizer Control Service, under state and federal authority.
- These inspections are focused on the the feed manufacturers and their related industries, including renderers, feed ingredient manufacturers, food/feed salvagers, integrated operations, ruminant feeders, on-farm mixer/feeders, and commercial transporters.
- All surveillance inspection results are shared with FDA.

Surveillance Samples

- Approximately 500 surveillance samples are collected annually by the Texas Feed and Fertilizer Control Service, under state and federal authority.
- These samples are analyzed by real time polymerase chain reaction (PCR) analysis and any presumptive positive samples are confirmed by microscopy.
- All surveillance sample results are shared with FDA.

FY 2010 Texas Surveillance Inspection and Sample Results

- 481 BSE inspections were conducted.
- 3 inspections resulted in a "notice of adverse inspectional observations" or FDA 483.
- 500 samples were collected and evaluated by real time PCR.
- 17 of the real time PCR evaluations resulted in DNA amplification with bovine primers, initiating microscopy evaluation for confirmation.
- 6 microscopy evaluations indicated the possible presence of non-exempt or prohibited protein materials.

FY 2010 Texas Surveillance Inspection and Sample Results

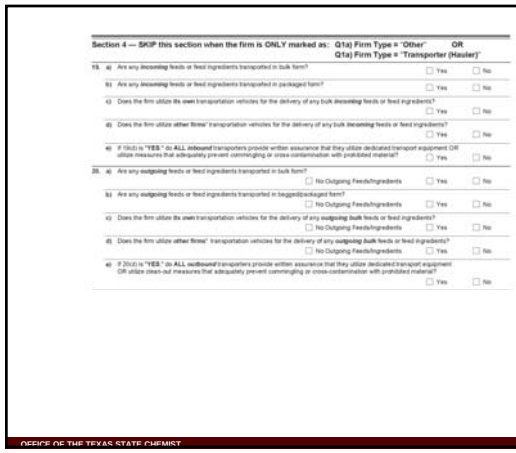
- **These 6 analytical results indicating the possible presence of non-exempt or prohibited protein materials resulted in trace-back investigations designed to determine the source or cause of the contamination and to document the corrective actions taken by the manufacturers to prevent the presence of any prohibited mammalian proteins in the future.**

REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000 and §589.2001

Section 1 — Complete for ALL firms

Section 2 — Complete for ALL firms EXCEPT: Firms that are ONLY Q1a) Firm Type = 'Other' OR Firms that are ONLY Q1a) Firm Type = 'Feeder of Ruminants'

Section 3 — COMPLETE this section ONLY if the firm is marked as: Q1a) Firm Type = "Renderer"



Section 4 — SKIP this section when the firm is ONLY marked as: Q1a) Firm Type = 'Other' OR Q1a) Firm Type = 'Transporter (Hauler)'

Section 5 — Complete this section ONLY if the firm is marked as: Q1a) Firm Type = "Feeder of Ruminants"

21. Are ruminant feeders doing the following?

a) Observing the caution statement on feeds containing prohibited material (PM) ☐ Yes ☐ No ☐ No PM-feeds on premises

b) Maintaining copies of labeling for feeds containing animal protein (AP) (Not including retail pet food for cats and dogs) ☐ Yes ☐ No ☐ No AP-feeds on premises

c) Maintaining copies of purchase invoices for feeds containing animal protein (Not including retail pet food for cats and dogs) ☐ Yes ☐ No ☐ No AP-feeds on premises

d) Feeding non-ruminant species (Not including cats and dogs) ☐ Yes ☐ No

e) Feeding non-ruminant species (Not including cats and dogs) feeds containing prohibited material ☐ Yes ☐ No ☐ No PM-feeds on premises

f) Feeding cats and/or dogs ☐ Yes ☐ No

Section 6 — Complete for ALL Firm Types

22. a) Check all deviations that were noted at the time of inspection. ☐ Commingling ☐ Labeling ☐ No Deviations Noted ☐ Recordkeeping ☐ Feeding Ruminants Prohibited Material

b) If any deviations were noted above, describe the deviations, and the actions and commitments made to correct each deviation.

23. a) Are you attaching any descriptions, exhibits, records, labeling, reports or supplemental information? ☐ Yes ☐ No

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Summary

- Bovine Spongiform Encephalopathy (BSE) or "mad cow disease" had a substantial impact for the livestock industry in the UK and other countries.
- The outbreak was amplified by practices of feeding animal protein from infected cattle to other cattle.
- Multiple firewalls developed by the USDA and FDA have effectively prevented the spread of the disease.
- Critical safeguards helping prevent the spread of BSE were the FDA 1997 and 2008 Animal Feed Ban Regulations.
- Over 76,000 inspections have been performed since the 1997 feed ban, around 72% by State feed control officials.
- There is high compliance with the regulations as a result of education and voluntary compliance.

END

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