### Safeguarding The Food Supply Against BSE

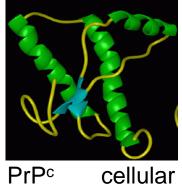


### What is BSE?

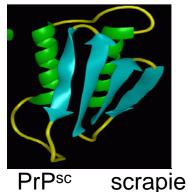
- BSE stands for Bovine Spongiform Encephalopathy
- Neurological disease of cattle
- Transmitted via feed and feeding practices
- Linked to variant Creutzfeldt-Jakob Disease in humans

# The Causative Agent

Normal Prion Protein



**Mis-folded Prion Protein** 

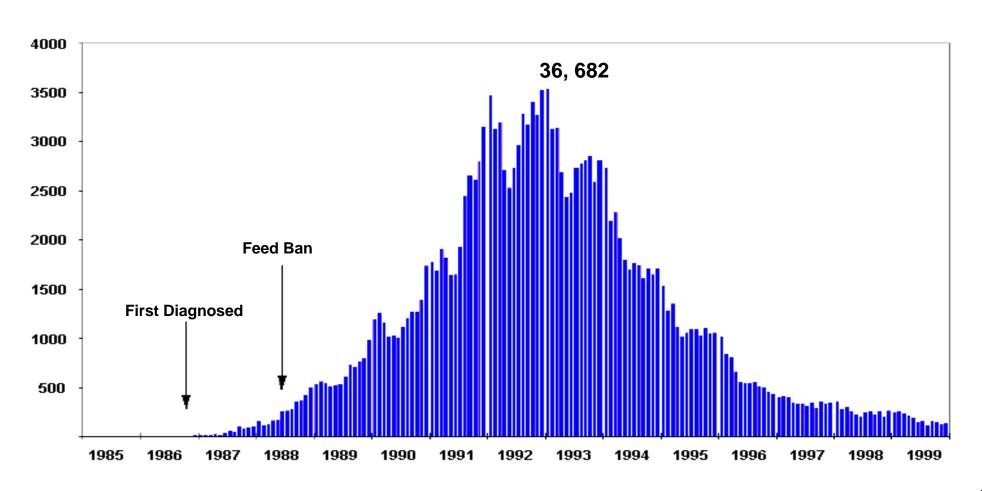


- Prion Protein Hypothesis: the causative agent of all TSEs is an abnormal form of the prion protein
  - PrPc occurs normally in vertebrates found at high levels in nervous tissue
  - Disease form resists breakdown and causes the normal form to mis-fold into the abnormal structure
  - Process takes approximately 5 years in cattle from exposure at calfhood until clinical disease

# **Animal TSEs**

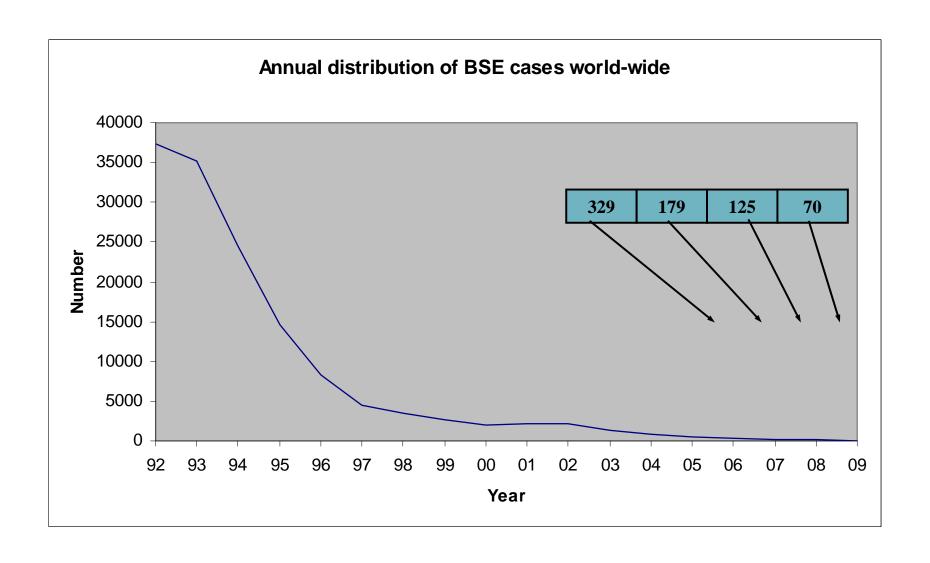
	Transmission	Tissue distribution	Known human susceptibility
scrapie	Lambing (placenta)	Lymph nodes, then central nervous system	No
CWD	Saliva feces	Lymph nodes, then central nervous system	No
BSE	Animal feed	Direct route to central nervous system	Yes

## **UK BSE Outbreak**



#### Annual Distribution of BSE Cases World-wide

Adapted from http://www.oie.int/eng/info/en\_esbmonde.htm



### Reported BSE/vCJD cases as of Dec 2009

#### BSE Total = 190,501 vCJD Total = 217

Adapted from http://www.oie.int/eng/info/en\_esbmonde.htm

Country	BSE	vCJD	Country	BSE	vCJD
Austria	6		Liechtenstein	2	
Belgium	133		Luxembourg	3	
Canada	18	1	Netherlands	85	3
Czech Republic	28		Poland	67	
Denmark	17		Portugal	1061	3
Finland	1		Slovakia	24	
France	1001	25	Slovenia	8	
Germany	417		Spain	742	5
Greece	1		Sweden	1	
Ireland	1646	4	Switzerland	464	
Israel	1		UK	184595	170
Italy	142	1	USA	3	3
Japan	35	1	Saudi Arabia		1

# Protecting the U.S. From BSE

- FDA Center for Veterinary Medicine
  - keep BSE out of the animal feed supply
- USDA Animal and Plant Health Inspection Service
  - keep foreign animal diseases out of U.S.
  - conduct disease surveillance
- USDA Food Safety and Inspection Service & FDA Center for Food Safety and Applied Nutrition
  - keep BSE out of the human food supply
- Other FDA Centers
  - protect the blood supply
  - protect drugs, biologicals, and devices made from bovine origin material

#### BSE Surveillance in the United States

- USDA > 1,000,000 cattle tested in the US since 1990
  - First case detected in Washington State in 2003
- Enhanced surveillance: June 1, 2004 August 20, 2006
  - 787,000 highest risk cattle
  - 1 case detected in Texas in 2005
  - 1 case detected in Alabama in 2006
- Ongoing surveillance
  - September 1, 2006 Present
  - Goal: 40,000 samples per year

## Ruminant Meat and Bone Meal (MBM)



- Provides valuable nutrients allowed for use in feed for all species until linked to BSE in the UK outbreak
- No longer allowed in ruminant feed

# Rendering Process



- Raw Materials:
  - slaughter by-products
  - livestock mortalities
- Cooking:
  - 245-290° F
  - 40-90 minutes
  - Evaporates water (50%)
- Yield:
  - Fat (25%)
  - Meat and bone meal (25%)

 If present, the rendering process reduces but does not completely eliminate the BSE agent.

## 1997 (Original) BSE Feed Regulation

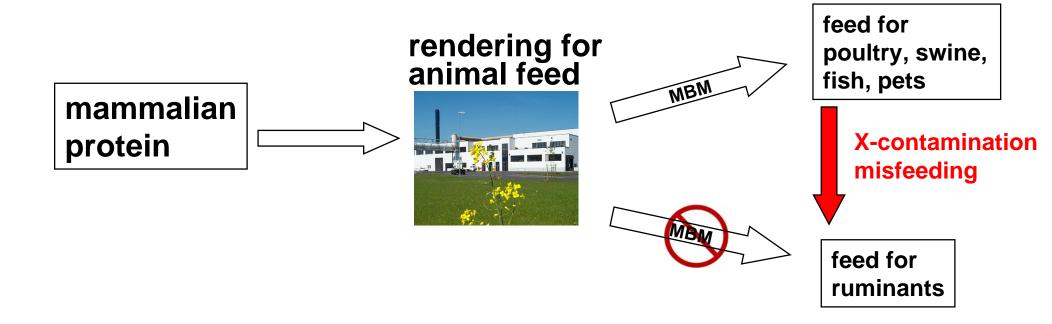
#### Prohibits feeding mammalian protein to ruminants

 Exceptions: milk products, blood products, gelatin, porcine/equine protein, and plate waste

#### Requirements

- Adequate measures for preventing cross-contamination
- maintain receipt, processing, and distribution records for one year (and make available for inspection)
- Label products with caution statement "Do not feed to cattle or other ruminants"

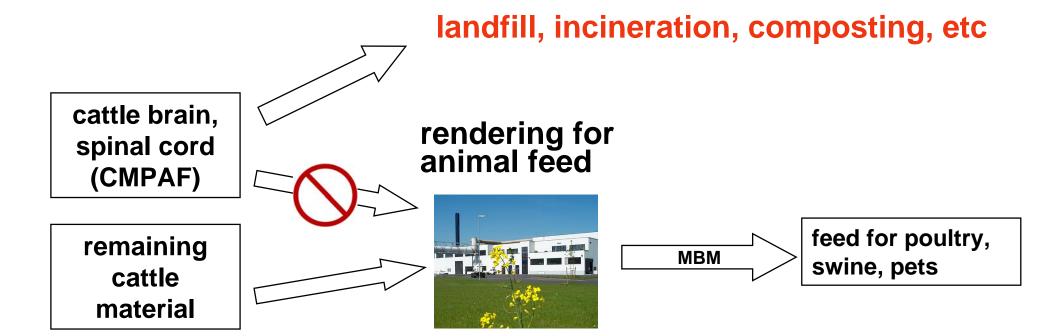
## 1997 BSE Feed Regulation (Feed Ban)



# 2008 BSE Regulation

- Published: April 25, 2008
- Compliance Date: October 26, 2009
- Prohibits for use in <u>ALL</u> animal feed material known as "cattle material prohibited in animal feed" (CMPAF)
  - CMPAF consists mainly of the brain and spinal cord from cattle 30 months of age and older

# 2008 BSE Feed Regulation

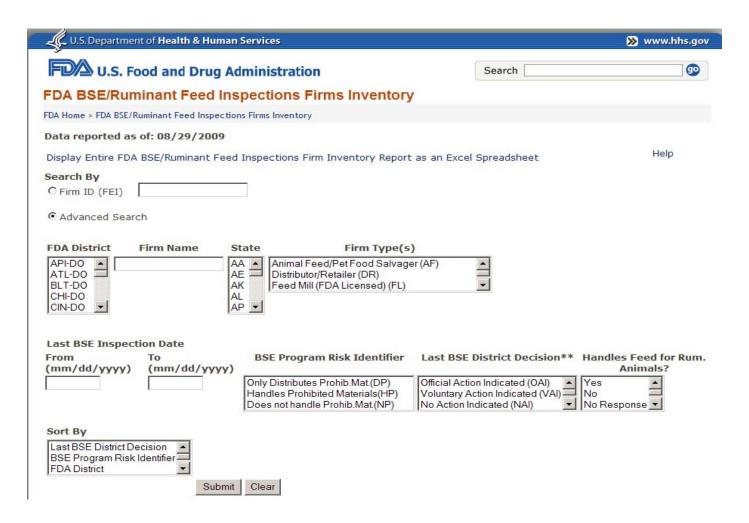


## Enforcement of the Feed Ban

- FDA and State Inspections
  - About 350 FDA HQ and field investigators
  - About 400 state inspectors
- More than 76,000 inspections since 1997, and about 8000 per year under current work plan
  - >70% conducted by state feed control officials
  - State inspection results submitted through FDA District BSE Coordinators
  - All inspections go into our FACTS database
  - Inspection summaries are viewable by the public on the internet

## Online Access to Inspection Results

Inspection Database: <a href="http://www.accessdata.fda.gov/BSEInspect/">http://www.accessdata.fda.gov/BSEInspect/</a>



# Feed Sampling & Analysis

- Testing is complex due to lack of a definitive analytical method
- Test for the presence of prohibited mammalian protein
  - no methods available to test feed for the BSE agent
- FDA uses feed microscopy and polymerase chain reaction (PCR) as our official methods
- FDA does not enforce based only on an adverse test
  - Follow-up investigation is needed to confirm findings

## Questions?

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