



April 22, 2014

Docket Number APHIS 2009-0017  
Regulatory Analysis and Development  
PPD, APHIS, Station 3A-03.8  
4700 River Road, Unit 118  
Riverdale, MD 20737-1238

**RE: Docket Number APHIS 2009-0017, Importation of Beef From A Region in Brazil**

The National Cattlemen's Beef Association (NCBA) welcomes the opportunity to comment on the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service's (APHIS) proposed rule for the importation of fresh, matured, deboned beef from a Region in Brazil into the United States. NCBA is the oldest and largest trade association for America's cattle farmers and ranchers, representing 140,000 cattle producers through direct membership and our state affiliates. NCBA is producer-directed and consumer-focused and our top priority is to produce the safest, most nutritious and affordable beef products in the world. **NCBA is strongly opposed to this proposed rule.**

NCBA's comments are based on a careful analysis of the proposed rule, the risk analysis, regulatory impact analysis, environmental assessment, and all accompanying supporting documents. Additionally, NCBA has requested information under the Freedom of Information Act (FOIA) from USDA APHIS related to actions taken on five APHIS site visits to Brazil (2002, 2003, 2006, 2008, 2013) to substantiate animal disease control measures, surveillance policies, and geographical border controls in order to establish an overall risk picture for the Region. Additionally, FOIA information requests were made to APHIS for documented reporting procedures, established methodology and management controls for the APHIS site visits as well as specific documents demonstrating proof of Brazil's governmental oversight and financial stability to successfully implement the risk mitigation outlined in the proposed rule.

A FOIA request was also made to USDA, Food Safety Inspection Service (FSIS) for information related to FSIS decision memos for the equivalency for Brazil, documents concerning Brazil's self-suspensions from 2005-2010, all documents related to Brazil's inability to enforce FSIS Bovine Spongiform Encephalopathy (BSE) inspection requirements from 2002-2013 and draft final 2013 FSIS audit for Brazil. Unfortunately, NCBA has failed to receive any of the requested FOIA documents from either agency in an appropriate time period. Given the failure to receive our requested information in a timely manner, NCBA is requesting an extension for an additional 120 days to comment to the proposed rule. NCBA is filing our comments to Docket- APHIS 2009-0017 as preliminary comments pending our receipt and review of all requested information from USDA APHIS and USDA FSIS under FOIA.

Many of NCBA's comments concerning the APHIS risk analysis reflect the findings obtained through a third party, objective, scientific review of the *APHIS Risk Analysis for the FMD Risk from Importation of Fresh, Maturated, Deboned Beef from a Region in Brazil into the United States* by a team of risk assessors from the University of Minnesota (UMN) College of Veterinary Medicine, Center for Animal Health and Food Safety, and the Center for Veterinary Population Medicine. The UMN team of reviewers included: Dr. Sarah Easter Strayer, Dr. Mac Farnham, Dr. Tim Goldsmith, Dr. Will Hueston, Dr. Kristen Johnson, Dr. Andres Perez, and Dr. Fernando Sampedro.

NCBA has long been a proponent of open trade markets, level playing fields and utilizing science-based standards to facilitate international trade. We believe that every effort should be made to develop an integrated domestic-foreign trade policy which encourages reciprocity, elimination of unfair trade restrictions and a movement toward private enterprise and free markets. At the same time, NCBA is committed to ensuring the continued health and well-being of the United States cattle herd and to producing safe and wholesome beef products for consumers. **While NCBA supports import rules based on scientifically informed principles and consistent with the World Organization for Animal Health (OIE) guidelines, NCBA does not support the proposed rule by USDA APHIS to import fresh beef from the Region in Brazil into the United States.** We have significant concerns regarding the willingness, committed resources, and infrastructure of Brazil to consistently perform adequate risk management in order to mitigate the risk for the introduction of FMD into the United States through the importation of fresh Brazilian beef.

NCBA is prepared to demonstrate scientific concerns with the current APHIS risk analysis for Brazil and to demonstrate a lack of transparency in the procedures for APHIS site visits used to verify animal health status information from the exporting country/region. We are able to verify a proven track record of Brazil's consistently poor performance in USDA FSIS food safety compliance audits from 2003 to 2013, which serves to cast significant doubt for the ability of Brazil to successfully perform the more stringent compliance measures necessary to mitigate the risk of FMD. NCBA will bring to light a past problem that Brazil has experienced in animal disease reporting that calls into question Brazil's aptitude for rapidly identifying and reporting a case of FMD in Brazil. Finally, NCBA will provide information from documented audits with Brazil's current trading partners in fresh beef and bovine products that illustrate deficiencies in Brazil's compliance practices.

In their risk analysis for the importation of fresh beef from a region in Brazil, APHIS acknowledges that the consequences of an FMD outbreak in the United States would be extremely high with direct impacts upon animal health and productivity and indirect impacts for personal livelihoods and the loss of trade and economic well-being for our country. When resuming or establishing trade with international partners, APHIS must keep in mind that their actions should strive to reflect the agency's mission to provide leadership on food and agricultural issues, based on sound policy, the best available science, and efficient management.

Foot-and-Mouth Disease (FMD) is an extremely contagious viral disease, primarily of cloven-hoofed animals and many wildlife species. The last documented outbreak of FMD in the United States occurred in 1929 and the last documented outbreak of FMD in the proposed export Region in Brazil occurred in 2006. A review of the literature of 627 documented outbreaks of FMD from 1870 through 1963 revealed that the majority of these outbreaks (>68%) were caused by the legal or illegal importation of infected animals or animal products.<sup>1</sup> Therefore, a first line defense against the introduction of FMD into a free area is to have adequate import controls and quarantine procedures for live animals as well as to establish proper risk analysis of the hazards associated with the importation of animal products from FMD affected areas of the world.

Currently, the United States Code of Federal Regulation (CFR) Title 9, Part 92.2 outlines a set of factors USDA APHIS must consider when evaluating the animal health status of a country or region requesting export of live animals or animal products to the United States. These factors were modified after 2012 to include: the scope of the evaluation; veterinary control and oversight; disease history and vaccination practices; epidemiological separation from potential sources of infection; livestock demographics and traceability; surveillance practices; diagnostic laboratory capabilities; and emergency preparedness and response. USDA APHIS conducts site visits to the requesting export region or country to verify data provided in response to the factors for evaluation for the animal health status and to gain a better understanding of the disease control and surveillance measures for the area. NCBA would advise APHIS that these factors for evaluating the health status of an exporting country should be considered as much more than a simple checklist for reviewers and that the consistent implementation of these factors should be **completely** verified.

### **APHIS RISK ANALYSIS FOR FMD RISK WITH THE IMPORTATION OF FRESH, MATURATED, DEBONED BEEF FROM A REGION IN BRAZIL**

The risk analysis conducted by USDA APHIS was published in December 2013 and appears to be based on five site visits to the proposed export region of 14 States in Brazil conducted in 2002, 2003, 2006, 2008 and 2013 to verify and complement the information provided by the records of the Ministry of Agriculture, Livestock and Food Supply (MAPA) in Brazil. The process of scientific risk analysis has been adopted by the OIE as the most appropriate scientific method for assessing the likelihood that a disease or disease agent will be spread through movement or trade of animals and animal products.

Not all of the factors for animal health status were reviewed at each of the site visits by APHIS. The scope of the 2002 visit included verification of FMD outbreak controls, an overview of the surveillance program and laboratory capabilities, vaccination practices and eradication activities and movement and border controls. The focus of the 2003 visit was to collect data that APHIS used in its risk assessment. The objective of the 2006 visit was to evaluate the FMD situation in Brazil following an FMD outbreak in 2005-2006 within the proposed export Region. The focus of the 2008 visit was to evaluate the

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<sup>1</sup> USAHA Committee on Foreign and Emerging Diseases, "Foot-and-Mouth Disease," Foreign Animal Diseases, (2008, 7<sup>th</sup> ed.), p. 272.

Brazilian State of Santa Catarina for freedom from classical swine fever, FMD, African swine fever, and swine vesicular disease. The scope of the 2013 visit included an evaluation of the FMD diagnostic capabilities, FMD laboratories and vesicular disease emergency response plans. It would seem that some of the factors, such as movement and border controls have not been verified through site visits since the 2002 site visit, twelve years ago.

NCBA requested additional information from APHIS regarding site visit reports or any documentation for the reviews conducted during these five site visits to Brazil between 2002 and 2013. APHIS verbally informed us that **no written reports or documentation of the site visits existed** as it is not a requirement for APHIS to document the site visits because the site visits are reviews and not audits. NCBA further requested through FOIA to APHIS all copies of the documents and emails associated with the five site visits to Brazil to include checklists, data analysis, reviewer's notes or interview notes. Additionally, we requested a copy of the USDA APHIS methodology for the reviews resulting from the site visits performed to verify information used in the risk assessment as well as all management controls for APHIS site visits. At the time of the current comment deadline, NCBA has failed to receive any of the requested information through FOIA from USDA APHIS.

NCBA is extremely concerned that the APHIS site visits, which are utilized by APHIS to verify information for the animal health status of the requesting export country or region and are critical to developing accurate conclusions for the risk assessment, have no apparent requirement for written documentation or reporting. We contend that even simple observations need a consistent method for documentation in order to provide indisputable verification and validity. There is no obvious evidence of any established protocol or methodology to allow for consistency and assurance in the quality of the APHIS site reviews. It is not clear from the risk analysis documents what data is verified through export country documents and what data is verified through APHIS site reviews. An obvious lack of management controls for the APHIS site review process questions the quality assurance for site reviews and threatens to erode the transparency and integrity of the entire APHIS risk assessment process. Currently, we believe that the APHIS process for site visits for animal health status review appears to lack transparency and violates an Administrative mandate to all Federal departments to operate in an exceedingly open, transparent, and accessible way for their stakeholders. Furthermore, Chapter 2.1 of the *OIE Terrestrial Animal Health Code* states that the risk analysis should be transparent. This is necessary so that the exporting country is provided with clear reasons for the imposition of import conditions or refusal to import. Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgment may blur<sup>2</sup>.

The **release assessment, exposure assessment and consequence assessment** appear incomplete with regard to the necessary steps and requirements outlined in the international standards as described in the *OIE Terrestrial Animal Health Code*, Chapter

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<sup>2</sup> OIE Terrestrial Animal Health Code, "Chapter 2.1, Import Risk Analysis," (2013, 22<sup>nd</sup> Edition, Vol.1, Section 2), p. 1.

2.1. The definitions for each of the risk terms in the risk assessment are lacking as well as a matrix for establishing the risk estimation. The data and scientific literature underpinning the assessment of risk for each of the pathways is limited.

In the **release (entry) assessment**, the biological pathways necessary for an importation activity to introduce pathogenic agents into a particular environment and the probability of the disease occurring are not clearly identified as directed in the *OIE Terrestrial Animal Health Code*. Instead, APHIS uses the factors for evaluating the animal health status of the region (CFR, Title 9, Part 92.2) to evaluate the FMD status of the export region in Brazil. The following points of concern exist within the APHIS release assessment:

- While the release assessment suggests that wildlife may be believed to play only a minor role in the transmission of FMD, the statement lacks supportive scientific literature and appears to be solely based on the opinion of the animal health officials in Brazil.
- NCBA believes that the risk of the reintroduction of FMD into Brazil exists as a result of the following situations: (1.) a large border area with “at risk” neighboring countries that is difficult to control (2.) the history of FMD outbreaks in areas of the export region under systematic vaccination (3.) the existence of regions in Brazil (Amazonia) not under sufficient FMD control (4.) the possible illegal movement of animals in which mitigation measures may reduce the likelihood of FMD infected cattle being transported to processing; but, the risk for FMD reintroduction into the export area still exists.
- Reviewers agree on the possibility of the occurrence of FMD-infected, but undetected, cattle passing through ante-mortem and post-mortem inspections and being processed for export to the United States. Mitigation measures that are designed to safeguard against the risk of FMD include deboning of meat, maturation for at least 24 hours, and pH measurements below 6.0 in the loin muscle. These measures appear in the OIE guidelines for the safe export of meat from FMD infected countries or regions with an official FMD control program with systematic vaccination. Interestingly, the reduction of pH is not included as one of the recognized procedures for the inactivation of FMD virus in meat in the *OIE Terrestrial Animal Health Code* Chapter 8.6, Article 8.6.34. Consequently, it seems that some of these mitigation measures need additional supportive data and references. The reference presented (Bachrach et al, 1957) is based on the effect of pH on viral survival in a buffer not in the meat and the review cited references the same study. No mention is made in the document regarding freezing procedures of carcasses processed to export to the United States. In order to effectively reduce the risk of FMD virus presence in meat, freezing should occur after maturation. If freezing occurs too early after slaughter, FMD virus present may survive for months.<sup>3</sup>

The **exposure assessment** identifies only a single exposure pathway through the feeding of FMD-contaminated beef to susceptible animals. There is no discussion of any

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<sup>3</sup> Cottral, G.E., Cox, B.F. and D.E. Baldwin, “The survival of FMD virus in cured and uncured meat,” *American Journal of Veterinary Research*, March 1960, 288-297.

alternative exposure pathways for FMD (illegal imports, back yard pigs feeding). The exposure assessment should focus on the effects of plate or manufacturing waste processing for swine feeding on the survival of FMD virus. According to federal regulations garbage needs to be processed at 167 degrees Fahrenheit (75 degrees Celsius) for at least 30 minutes or to a minimum temperature of 230 degrees Fahrenheit for rendered product. Data is not contained in the exposure assessment on the combination of temperature-time for the processing of table waste and its effect on FMD virus survival. The exposure assessment and the percentage of feeding inadequately processed plate waste to swine (0.023%) are based on a 1995 APHIS Veterinary Services pathway analysis for exposure of swine to infected plate and manufacturing waste. This 1995 analysis is outdated and incomplete. APHIS needs to consider obtaining updated scientific data, independent of the previously cited unpublished 2001 APHIS waste-feeder survey, in order to better verify the exposure assessment for FMD presented in the risk analysis.

The **consequence assessment** needs to be focused on the specific commodity as outlined in the scope of the risk assessment. The scope of the risk assessment is described as the risk for infecting susceptible livestock in the United States with FMD virus through importing fresh, maturated, deboned beef from the export Region in Brazil.

A risk assessment can be either quantitative, providing a numeric estimation of the probability of risk and the magnitude of consequences, or qualitative, using a descriptive approach. Qualitative risk assessments are often criticized due to their increased potential for subjectivity and their limitations to extend and better define the range of adjectives used to describe the lower probabilities and to assess consequences. Quantitative risk assessments allow an assessment of specific risk concerns, testing of assumptions, analysis of uncertainty and evaluation of the effectiveness of proposed mitigation measures.

The 2013 APHIS risk assessment for the risk of FMD from the importation of fresh beef from a region of Brazil is a **qualitative** risk assessment. The 2002 APHIS risk assessment for the importation of fresh beef from Uruguay is a **quantitative** risk assessment. The objective of the Uruguay risk assessment is to **quantify** the actual risk for the introduction of FMD virus into the United States through the importation of fresh, maturated and deboned beef cuts from a vaccinated cattle herd population in Uruguay. Both Brazil and Uruguay are recognized by the OIE as “FMD free with the practice of vaccination.” **NCBA contends that the magnitude of the possible consequences of the introduction of FMD into the United States from fresh beef from Brazil requires a more rigorous analytical process, such as a quantitative risk assessment, to objectively identify risks and to apply effective mitigations that best safeguard animal health in the United States.** Why did APHIS elect not to perform a quantitative risk analysis for Brazil as was performed for Uruguay regarding the FMD risk from the importation of fresh beef into the United States? Why was **disparate treatment** by APHIS shown in developing the risk assessments for these two countries with the same FMD status recognition by the OIE and for the same import commodity?

## **BRAZIL HAS CONSISTENTLY DEMONSTRATED COMPLIANCE PROBLEMS WITH ROUTINE USDA FSIS AUDITS (2003 to 2013)**

USDA FSIS ensures that meat, poultry, and egg products imported to the United States are produced under standards equivalent to U.S. inspection standards and facilitates the certification of exported goods. USDA FSIS provides comprehensive audits of foreign country inspection systems to guarantee compliance with the regulatory requirements of the Federal Meat Inspection Act, the Poultry Products Inspection Act and the Egg Products Inspection Act. A review of Brazil's performance in FSIS audits from 2003 to 2013 documents a pattern of behavior demonstrating that Brazil appears unable to execute a consistent program of adequate oversight. Brazil's inability to comply with equivalency for U.S. inspection standards challenges the ability of Federal and States' authority in Brazil to consistently enforce mitigation measures to prevent the introduction of FMD into the United States through the importation of fresh beef. A summary of Brazil's oversight problems for basic U.S. inspection standards is provided as follows.

USDA FSIS audits in 2003 and 2004 identified systemic failures in Brazil's meat inspection system. In 2003, Brazil claimed to be using certain laboratory procedures and methods to test for residues and pathogens, but the United States found that those procedures and methods, in fact, were not being employed. In 2004, the United States determined that the Brazilian Central Competent Authority did not maintain direct oversight over the laboratories where testing for residues was being performed. Based on the problems identified in these audits, FSIS conducted an enforcement audit in 2005 (March 10-April 14, 2005) and three follow up audits (June 2-23, 2005; July 7-27, 2005 and October 19-November 7, 2005) to verify the implementation of corrective actions in response to enforcement audit findings. During the March/April 2005 enforcement audit, serious deficiencies were found in all aspects of government oversight; the payment of inspectors in Brazil with the use of establishment-paid inspectors creating conflict of interest issues; concerns with laboratory operations; concerns with establishment operations; and residue compliance issues. As a result, Brazil voluntarily suspended all of the country's establishments certified for meat export to the United States in April 2005. In December 2005, FSIS notified the government of Brazil that it had regained eligibility to certify meat establishments for exports to the United States. The decision was based on the positive results of the three follow-up FSIS enforcement audits, which verified that Brazil had implemented corrective actions regarding meat inspection system failures that were noted in the March/April 2005 enforcement audit. Unfortunately, in 2008, Brazil again was forced to **"self-suspend"** all of the country's slaughter establishments for the second time in three years because the Brazilian Central Competent Authority was not in control of the country's food safety system.

On May 27, 2010, Brazil notified USDA FSIS that it was voluntarily suspending all exports of cooked beef products to the United States effective immediately as a result of adulterated product. The adulterated product resulted from Ivermectin (broad spectrum deworming agent) residues in violation of the FDA level of 10 ppb. This adulterated product was discovered in nine samples on March 15, 2010 through port of entry sampling in the United States. Starting on May 10, 2010, increased sampling for all Brazilian beef products entering the country revealed additional adulterated product in

commerce and at port of entry locations. On May 27, 2010, Brazil requested assistance in obtaining the methodology used by FSIS to detect Ivermectin in Brazilian meat products exported to the United States. This request greatly concerned FSIS, as it seemed to indicate that Brazil has not been previously testing muscle products in an equivalent manner with the United States standards.

FSIS completed their most recent audit of Brazil in 2013. NCBA requested the draft 2013 FSIS audit for Brazil through a FOIA information request. The draft 2013 FSIS audit is considered by USDA FSIS to be “pre-decisional” and not publicly available through FOIA request until the 2013 FSIS audit is finalized. At the same time, recent news reports indicate that Ivermectin residue issues persist in processed beef coming into the United States from Brazil, with the failure of Brazil’s Ministry of Agriculture to respond to a March 2013 deadline to report changes in the country’s prevention system for Ivermectin residues as a follow up to a 2013 inspection by the United States. Reports further indicate the desire by federal officials in Brazil to ban the use of Ivermectin; however, the cattle industry in Brazil is resisting this move as a possible solution to the country’s residue problems. Information also suggests that the 2013 FSIS audit for Brazil may detail issues with Brazil’s BSE/SSM control. **Brazil’s poor compliance record with FSIS audits can be best summarized by the need for Brazil to “self-suspend” all of their slaughter establishments certified to export to the United States three times between 2005 and 2010.** Will the recent persistent Ivermectin residue issues result in yet another “self-suspension” for Brazil?

Brazil has a responsibility to demonstrate that the Central Competent Authority in Brazil exercises a level of control over its food safety system to ensure that the products produced by that system are safe and wholesome. To maintain equivalency, a country must demonstrate the ability of the Central Competent Authority to identify and resolve design and implementation concerns such that product exported to the U.S. meets the same sanitary measures as product originating within the United States. Brazil has a long history of problems maintaining such a level of control. Brazil’s failure of control in equivalency measures strongly suggests that a similar inability may exist to consistently execute risk management measures and ensure that mitigation measures are in place to manage the risk for FMD from the importation of fresh beef from regions in Brazil into the United States. Given Brazil’s poor past performance record with compliance in food safety through FSIS audits, should U.S. cattlemen and women feel secure that the health of the U.S. cattle herd can be adequately safeguarded through the FMD risk mitigation measures, whose consistent and correct execution are the responsibility of Brazil’s Central Competent Authority? Will appropriate maturation times for carcasses be followed? Will consistent pH testing of carcasses take place? Will there be adequate ante-mortem and post-mortem inspections? Will verifications of the mitigations by Brazilian officials be performed appropriately? While we believe that these mitigation measures will be instituted, we are concerned that the mitigation measures, as directed by the OIE guidelines, will not be consistently and adequately implemented in Brazil.

## **BRAZIL HAS DEMONSTRATED RECENT PROBLEMS WITH ANIMAL DISEASE REPORTING**

APHIS concluded in their risk assessment regarding the animal health status in the export region of Brazil that MAPA could detect disease quickly, limit its spread, and report promptly, as demonstrated by the FMD outbreaks in 2005 and 2006 in which FMD cases were quickly identified and international authorities notified in a timely manner. APHIS does not appear to have updated their assessment of the ability of Brazil to report animal disease promptly since their 2006 evaluation. The APHIS site visits to Brazil in 2008 and 2013 did not focus on FMD outbreak controls or reporting capabilities. **More importantly, Brazil demonstrated a significant problem with animal disease reporting in 2010 when MAPA failed to promptly identify and report the country's first case of Bovine Spongiform Encephalopathy (BSE).**

An animal infected with BSE died in Brazil in December 2010. Initial testing of this same animal in Brazil in early 2011 produced test results suspicious for BSE. It was not until June of 2012, through testing of the brain of this deceased animal at the National Reference Laboratory in Recife, Brazil that a diagnosis of BSE was confirmed and reported to the OIE in July of 2012. The OIE Commission reprimanded Brazil for the **considerable 18 month delay in reporting** the disease as well as the delay in sending the appropriate samples to the OIE Reference Laboratory for confirmation. Brazil's reasoning given to the OIE Commission for their delay in animal disease reporting was related to laboratory work overload present in Brazil's laboratory system. Does this same problem of laboratory work overload still exist today in Brazil's laboratory system? Would the identification and reporting of a case of FMD be similarly delayed as a result of problems with excessive laboratory workload in Brazil?

In February 2013, the OIE Commission requested detailed information from Brazil concerning the processes in place for managing laboratory samples in Brazil. Brazil was cautioned by the OIE that the OIE would be monitoring for improvements in the surveillance system for identifying and reporting animal diseases in Brazil. NCBA urges APHIS to reevaluate Brazil's current ability to identify and report disease and not to simply rely on Brazil's past performance in 2006. As we have already demonstrated, Brazil has shown a history of problems in consistently maintaining compliance and controls.

## **DEFICIENCIES NOTED IN EUROPEAN COMMISSION AUDITS FOR BRAZIL REGARDING THEIR FRESH BEEF TRADE**

In 2012, the European Union (EU) imported 48,353 tonnes of fresh beef from Brazil, which represented 5.8 percent of Brazil's total fresh beef exports for that time period.<sup>4</sup> The European Commission performs regular audits in foreign countries exporting products to the EU member nations. NCBA reviewed four of the most recent audits of the

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<sup>4</sup> European Commission, Health & Consumers Directorate-General, "Evaluation of the Operation Controls over the Production of Fresh Bovine Meat and Casings Destined for Export to the European Union, as well as Certification Procedures," Final Audit Report, (March 2012), p. 2.

European Commission for Brazil (2008, 2010, 2011, 2012). These audits, by the European Commission to verify the necessary requirements for the import of fresh meat into the EU, showed deficiencies in Brazil's system in the areas of animal movement controls, adequate maintenance of slaughter facilities in Brazil, animal welfare concerns, and residue compliance issues for the veterinary drug, Ivermectin. These audits were all conducted within the export Region of Brazil involved in the current APHIS proposed rule.

A common denominator in the deficiencies noted from Brazil in the FSIS audits and the European Commission audits is a failure on Brazil's part to promptly institute and maintain corrective action for the deficiencies noted in previous audits. Brazil seems to lack either the willingness or the infrastructure to execute consistent management controls. NCBA strongly believes that Brazil cannot be relied upon to uniformly execute the necessary risk management steps required to sufficiently mitigate the risk of the introduction of FMD into the United States through the importation of fresh beef.

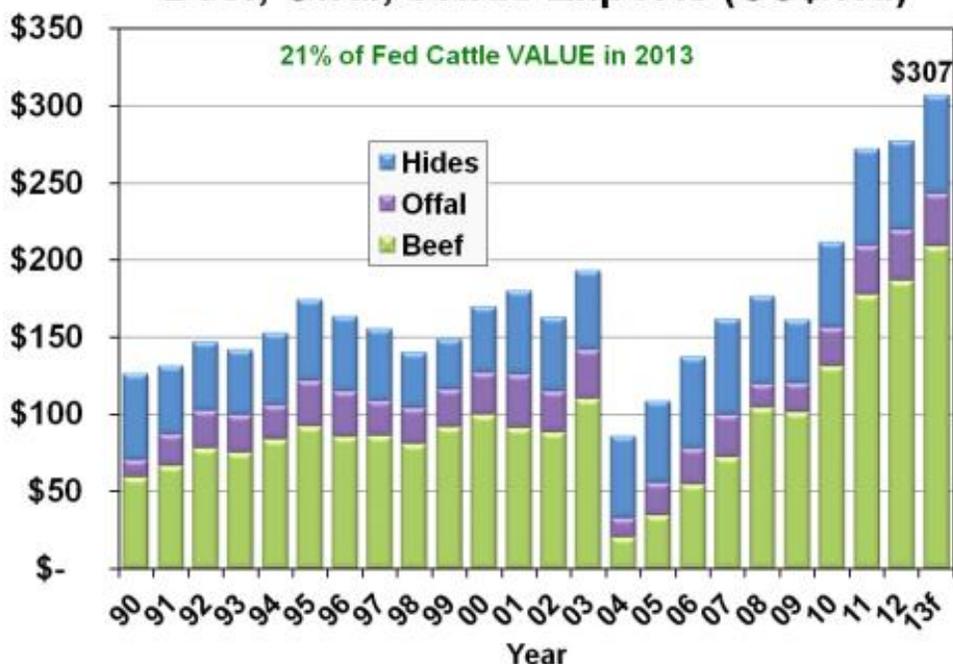
### **ECONOMIC IMPACT OF AN FMD OUTBREAK IN THE UNITED STATES**

As NCBA evaluated this proposed rule, we discovered that the economic impact of allowing the import of fresh (chilled and frozen) beef from certain regions in Brazil was not adequately addressed. As noted in the *Federal Register*, this rule is a significant rule, but the agency readily acknowledges that they do not know how this rule may affect the benefits or costs to small entities. The rule continues to state that "most of the establishments affected by this rule would be small entities..." This further underscores our concerns that the agency did not adequately prepare for the publication of this proposed rule. While we appreciate the agency's willingness to solicit comments specific to these small entities, we would have expected more research by the agency before moving forward. It is one thing to seek comments on different provisions included in the proposed rule, but a very different thing to admit in the rule that you do not know the effects on the entities the agency expects to be impacted the most. This lends itself to our overall concerns on the lack of appropriate process related to the formulation of this proposed rule.

The proposed rule ultimately estimates the impact on producers between 2014 and 2018 will be a loss of \$165 million. These losses are concerning, but are even more concerning because the agency failed to factor in the economic impact on United States beef producers in the event of reintroduction of foot-and-mouth disease (FMD) due to the access provided by this rule to certain regions in Brazil. A more accurate economic analysis should address the potential impacts on U.S. producers by looking at how FMD could impact our export markets and the losses incurred by producers who have infected herds.

In looking at the economic impact on producers, we will start with the value of export markets to our industry. According to this chart from CattleFax, exports of beef, offal, and hide are worth \$307 per head. This equates to twenty one percent of the value of fed cattle in 2013.

## Beef, Offal, & Hide Exports (US\$/Hd)



Source: USDA/FAS, CattleFax

**CattleFax** | THE DECIDING FACTOR

We expect that a case of FMD in the United States would result in immediate closure of most, if not all, of our foreign markets. Overnight, we could see up to twenty one percent of our fed cattle value evaporate. To put this in perspective, we need to look at the economic impact of the case of bovine spongiform encephalopathy (BSE) found in a Canadian-born cow located in Washington state on December 23, 2003. On January 2<sup>nd</sup>, 2004, February live cattle futures fell nineteen percent, April futures were down fourteen percent, and June futures were down nine percent due to the foreign market closures, market uncertainty, and consumer response. Cash prices for fed cattle averaged twelve percent lower in January and February of 2004 versus where those prices were in December of 2003 before the discovery of the cow with BSE. Normally, the cash prices in January and February should be two percent higher than December cash prices.

As a result of this case of BSE, we saw U.S. beef exports decline by two billion pounds from 2003 to 2004. It took until 2011 (eight years later) for U.S. beef exports to get back to pre-December 23, 2003, levels. A decade later, even though we have now exceeded pre-December 23<sup>rd</sup> export levels, we still do not have access to several critical markets such as China, nor do we have full access to every country we were trading with prior to December of 2003.

Given our belief that the foreign market response we saw with BSE would be similar to FMD allows us to estimate the economic impact we could anticipate. According to CattleFax, in using the 2003 case of BSE as a gauge in today's dollars, we would expect to see a decrease of two hundred dollars in the value of fed cattle on a per head basis. We

harvest approximately twenty five million fed steers and heifers a year. Therefore, a \$200 per head decrease in price on twenty five million head would equal a loss of five billion dollars. This is a loss based only on the closure of foreign markets. Individual country responses could cause this figure to be higher or lower, but this gives us an accurate estimate of the economic impact. A loss of five billion dollars would be crippling for our industry.

In the Department of Homeland Security's October 2010 "Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment" conducted for the National Bio and Agro-Defense Facility, it is noted on page 306 that in addition to the trade bans we might see imposed by foreign governments, we would also see effective trade bans which "reflect the changes in commerce (e.g., consumer behavior) that can augment the impacts of actual trade bans or cause significant economic disruption in the absence of any officially mandated ban." A great example of an effective trade ban would be what we are currently experiencing with U.S. beef exports to South Korea. South Korea was one of many foreign markets which shut out U.S. beef after December 23, 2003. Thanks to efforts by the United States Government and successful passage of the United States-Korea Free Trade Agreement, we were able to get a trade deal for beef based on the guidelines provided by the World Organization for Animal Health (OIE). Even though the official agreement allows beef trade to include beef and beef products from animals over thirty months of age, the U.S. beef industry has imposed our own voluntary ban on those products until we can regain the confidence of the South Korean consumer. It is unknown how long that could take.

It's not just the international trade impact which concerns us. In addition, we expect to see significant economic impacts to U.S. beef producers due to depopulation, restrictions on cattle movements, and a potential shutdown of overall cattle trade in the affected regions. There are many different variables which affect how we may see introduction of the disease and its spread. These variables include the region of the country, the type of operation, the timely reporting of the disease and the response time.

In a 2006 report titled "Invasive Species Management: Foot-and-Mouth Disease in the U.S. Beef Industry," Zhao, Wahl, and Marsh discuss these variables and propose several mathematical equations which can be used to model the economic impact of FMD. In a 2007 report titled "The Economic Impacts of a Foot-and-Mouth Disease Outbreak: A Regional Analysis," Pendell, Leatherman, Schroeder, and Alward look at similar mathematical approaches and model an outbreak of FMD in 14 counties in southwestern Kansas. In this report (Pendell, et al., 2007), FMD is modeled based on introduction at a cow/calf operation, a medium sized feedlot, and at five large feedlots. Based on their modeling, Pendell, et al. conclude that FMD introduction would cost the beef industry in southwestern Kansas \$43.2 million if the disease were introduced in a single cow-calf herd, \$166.5 million if introduced in a medium-sized feedlot, and \$728.5 million if introduced in five large feedlots. When they take the five large feedlot scenario and model it for the economic impact on the entire Kansas economy, they show an overall economic impact which would reach nearly \$1 billion.

It is important to note that the southwestern Kansas examples would also impact beef production and the economies of the surrounding beef producing states (Texas, New Mexico, Oklahoma, Colorado), as well as the rest of the industry. It is also important to note that these models were based on 2007 cattle prices. In 2007, the average price of fed cattle was \$92 per hundredweight. Projections are for fed cattle to average \$140 per hundredweight in 2014, making the economic impact today that much more.

In the “Site-Specific Biosafety and Biosecurity Mitigation Risk Assessment” conducted for the National Bio and Agro-Defense Facility, similar models are used to estimate the economic impact of an outbreak of FMD. In Table 5-21 found on page 341, the results are shown for several scenarios. In scenarios which model the economic impact of FMD on cow-calf operations, feedlots, and livestock markets, the total economic impact of a case of FMD can reach over \$50 billion in losses to the U.S. beef industry. Again, we must note that this report was based on 2010 cattle prices where the average fed cattle price was \$95 per hundredweight.

Regardless of the model or scenario used, it is obvious from the information above that the reintroduction of FMD would cost our industry billions. This alone justifies our concerns with the process used to formulate this rule. Too much is at stake with this proposal.

## **CONCLUSIONS**

NCBA has a number of questions for APHIS concerning the conclusions drawn in the APHIS risk analysis for Brazil. We maintain our previously established questions regarding Brazil’s ability for early disease reporting and question the success of the laboratory system in Brazil in recovering and isolating FMD virus from an early outbreak. What part might wildlife play in the risk for an FMD outbreak in Brazil? How porous are the borders in regions of higher risk for FMD, like the Mato Grosso do Sul/Paraguay border, the southern portion of which is characterized by 700 km of open, dry land with few physical barriers to hinder animal movement? Are there precautions taken at the higher FMD risk borders with countries such as Bolivia and Paraguay for fomite transmission of the FMD virus? Has Brazil considered that greater market opportunities and subsequently higher prices offered in the export Region might foster illegal animal movements and are there sufficiently stringent procedures in place in Brazil to restrict illegal animal movements into the export Region? Vaccination compliance tables provided in the APHIS risk analysis are dated from 2002 and 2006. Farmers in Brazil may vaccinate their own animals against FMD or hire trained professionals who do not have to be registered or accredited by government officials. FMD vaccine is sold by the bottle and not by individual animal doses, possibly making the vaccine more expensive for the small farmer. Is the vaccination coverage currently sufficient in the export Region of Brazil for FMD, a virus with a high reproductive rate?

Given the enormous economic damage that would occur in the United States if this proposed rule is flawed and allows FMD virus to enter our country and to infect our naïve cattle herd, NCBA believes that APHIS should be obligated to perform a complete

economic analysis for the impact to animal agriculture from the occurrence of an FMD outbreak in the United States. This should be performed as part of the regulatory impact analysis that accompanies this proposed rule. The current regulatory impact analysis performed by APHIS only considers the economic impact to the domestic beef market of adding an average amount of 40,000 metric tons of fresh beef annually from Brazil to the U.S. marketplace. This volume of fresh beef represents just 13 percent of the beef currently received from our largest import market. NCBA wants to express our extreme concerns for the possible economic and animal health consequences if the FMD virus should enter the United States as a result of the proposed rule. The APHIS regulatory analysis highlights possible consumer benefit from the import of 40,000 metric tons of fresh beef annually from Brazil but, fails to address the economic impact on consumers for the possible risk for the introduction of FMD virus into the United States.

On the basis of our significant concerns with Brazil's ability to consistently perform the required risk management for mitigating the FMD risk, NCBA respectfully requests that APHIS consider **withdrawing the APHIS proposed rule to import fresh, maturated, deboned beef from the Region in Brazil into the United States.** If the withdrawal of the APHIS proposed rule is not possible at this time, then NCBA would strongly advocate that APHIS take the following actions to better inform their decisions prior to any final rule-making:

- ❖ Perform a **quantitative** risk analysis for the risk of FMD from the importation of fresh, maturated, deboned beef from a Region in Brazil into the United States in order to reduce subjectivity and to provide a better analysis of uncertainty and the effectiveness of mitigation measures for the FMD risk, given the high consequences of the involved FMD risk.
- ❖ Establish protocols for documentation and a standardized methodology for the APHIS site visits/reviews in order to ensure adequate transparency and to implement needed management controls for quality assurance in decision-making and continued oversight.
- ❖ Update the scientific information used to verify the exposure assessment and confirm any numbers used within the exposure risk.
- ❖ Refocus the consequence assessment to align with the scope of the risk assessment.
- ❖ Provide additional scientific data to support risk mitigation measures, especially regarding maturation times and pH levels for muscle meat.
- ❖ As a critical part of the regulatory impact analysis associated with the proposed rule, perform a comprehensive up-to-date economic analysis to identify the economic consequences to all of the affected commodity groups in U.S. animal agriculture from a possible FMD outbreak in the United States.
- ❖ Coordination and information sharing with USDA FSIS when performing risk analysis to better establish a complete picture of compliance for animal health and food safety control measures by the requesting export country or region.
- ❖ Develop an ongoing APHIS oversight protocol to monitor Brazil's compliance with risk mitigation beyond the usual port of entry testing. We cannot comfortably rely on a self-reporting system in Brazil.

Regionalization on highly communicable animal diseases is possible if appropriate and extremely rigorous firewalls are put in place to safeguard against the risk for animal disease and to ensure compliance with all of the established risk mitigations. The risk to U.S. animal agriculture and to our cattle producers is far too great and the economic and animal health consequences too significant to move forward with this proposed rule without better establishing that an attitude of compliance and a sufficiently sophisticated infrastructure are present in Brazil to consistently perform all risk mitigation measures. Additional questions need to be answered and additional work needs to be done by APHIS to secure the necessary information to make responsible decisions that will safeguard the health and well-being of livestock in the United States.

We appreciate the opportunity to review and comment on this important rule. We look forward to working with USDA APHIS on the issues raised in our comments and to monitor implementation of any final rule. If you have any questions or concerns, please contact Dr. Kathy Simmons, NCBA's Chief Veterinarian at 202-347-0228 or at [ksimmons@beef.org](mailto:ksimmons@beef.org).

Sincerely,

A handwritten signature in black ink that reads "Bob McCan". The signature is written in a cursive, slightly slanted style.

Bob McCan  
President, National Cattlemen's Beef Association