



**R-CALF USA's Concerns for APHIS' Proposal to Regionalize 14 Brazilian States
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**A. APHIS' Risk Evaluation Methodology Is Incapable of Accurately Assessing the Risk for
FMD Outbreaks in Countries with Histories of FMD**

R-CALF USA presumes that like APHIS' previous evaluation for the regionalization of Brazil, the agency's current evaluation of Brazil was conducted according to the 11 factors identified in 9 CFR § 92.2, "Application for recognition of the animal health status of a region."

Importantly, the 11 factors relied on by APHIS to evaluate the potential for dangerous and destructive communicable diseases to enter the United States were not developed for the purpose of preventing the introduction of such diseases. Instead, they were developed pursuant to international trade agreements and at the behest of the international trade facilitating body known as the Office International des Epizooties (World Organization for Animal Health or OIE). For example, APHIS' original, 1996 proposed rule to relax U.S. disease restrictions by allowing regions within FMD-affected countries to nevertheless import higher-risk products into the United States was proposed for the express purpose of achieving compliance with "U.S. obligations under NAFTA-SPS and WTO-SPS with respect to the importation of live animals and animal products." 61 Fed. Reg., 16979, col. 1. As was the agency's final rule to relax U.S. disease restrictions: "The fundamental purpose of the changes we are making to the regulations . . . is to fulfill U.S. commitments under international trade agreements." 62 Fed. Reg., 56010, col. 2. And, ". . . our overriding goals in implementing regionalization are to facilitate trade in accordance with international agreements. . ." 62 Fed. Reg., 56005, col. 1. Moreover, APHIS granted complete and total deference to the OIE, thus abrogating its congressional mandate to protect U.S. livestock from the introduction of dangerous and destructive diseases, when, in 2001, it resumed imports of high-risk products from Japan on the basis that, "According to international disease standards set by the Office International des Epizooties . . . that country [Japan] can regain its FMD-free status 3 months after the last case. Therefore . . . we have determined that Japan meets *our* requirements for being recognized as free of FMD." 66 Fed. Reg., 46228, col. 3 (emphasis added).

Using those *same* 11 factors incorporated into U.S. disease regulations by international, rather than national, interests and by granting deference to the OIE, APHIS previously concluded that the countries/regions of/in Argentina, Uruguay, South Africa, South Korea and Japan were free of FMD. Subsequently, however, each of those countries/regions experienced widespread FMD outbreaks, which belied APHIS' conclusions that they were free of FMD.

**1. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD
Risks in Argentina**

In August 1997, APHIS engaged in a high-risk scheme to begin importation of fresh (chilled or frozen) beef from Argentina, even though Argentina was still carrying out vaccination for FMD. *See* 62 Fed. Reg., 56003, col. 2. APHIS claimed that this new scheme “exemplified the opportunity” to regionalize countries with ongoing FMD problems. *See id.* In July 2000, APHIS fully implemented a regionalization scheme for Argentina by prohibiting the importation of beef from animals that had been in specified areas along Argentina’s border. *See* 65 Fed. Reg., 82894, col. 1. In August 2000, just days before the effective date of APHIS’ regionalization rule, Argentina confirmed a new outbreak of FMD. Nevertheless, APHIS concluded the U.S. could continue to safely import fresh (chilled or frozen) beef from Argentina under its regionalization scheme, despite this new outbreak. *See id.*, 82894, col. 3. For nearly a year after its August 2000 outbreak, Argentina remained eligible to export fresh (chilled or frozen) beef to the United States. APHIS, however, was subsequently forced to take emergency, retroactive action in June 2001 to protect U.S. livestock from the introduction of FMD from Argentina because at that time APHIS believed the FMD virus already was present in Argentina for several weeks before Argentina finally reported the first of many new and widespread FMD outbreaks beginning in March 2001. *See* 66 Fed. Reg., 29897, col. 3; 29898, col. 1. APHIS’ regionalization scheme for Argentina was an abject failure that could have easily resulted in the introduction of FMD into the United States.

2. APHIS’ Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in Uruguay

In July 2000, APHIS was allowing fresh (chilled or frozen) beef from Argentina provided it was not from Argentina cattle that had been in close proximity to Uruguay. In October 2000 APHIS regionalized, retroactively, Uruguay by removing only Artigas, a department in Uruguay, from the list of regions considered by the U.S. to be free of FMD. *See* 65 Fed. Reg., 82894, col. 3; *see also* 65 Fed. Reg., 77772, col. 1. APHIS had evaluated Uruguay’s risk for FMD and concluded it was safe for the U.S. to continue the importation of fresh (chilled or frozen) beef from Uruguay provided it was not from cattle in Artigas, a region APHIS determined to qualify as a distinct subpopulation for disease control and international trade purposes under its regionalization scheme. *See* 65 Fed. Reg., 77771-773. However, within about four months of USDA’s presumed scientific conclusion that it was safe to continue the importation of beef in all regions of Uruguay except Artigas – a conclusion presumably based on a careful, scientific risk analysis – widespread FMD outbreaks were reported, beginning in April 2001, in numerous Uruguayan departments. *See* 66 Fed. Reg., 36695-697. By June 22, 2001, there were 1,596 new cases of FMD confirmed in 18 separate departments in Uruguay. *Ibid.*

3. APHIS’ Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in South Africa

After conducting an on-site visit along with a risk evaluation regarding the risks for FMD in South Africa, APHIS, in April 2000, regionalized the Republic of South Africa and declared it, except the FMD-controlled area (which includes Kruger National Park) free of FMD. *See* 64 Fed. Reg., 7819, col. 2 and fn 1; *see also*, 66 Fed. Reg., 9641, col. 1. In September 2000, APHIS was forced to take emergency action to protect U.S. livestock after a FMD outbreak was

confirmed in KwaZulu-Natal, a province in the Republic of South Africa. *See* 65 Fed. Reg., 65728, col. 1; 65729, col. 1. APHIS, however, persisted with its regionalization scheme and simply carved out KwaZulu-Natal as a province ineligible to export fresh (chilled or frozen) beef to the U.S. due to FMD. *See* 64 Fed. Reg., 65728, col. 3. Within a matter of months, in November 2000, APHIS was again forced to take emergency action to prevent the introduction of FMD into the U.S. by removing all of the Republic of South Africa from the list of regions considered free of FMD following new outbreaks of the disease in additional provinces.

4. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in South Korea

After South Korea experienced outbreaks of FMD in 2000 and 2002, APHIS, in October 2008, completed a comprehensive, 56-page evaluation of the risks for FMD in South Korea and determined South Korea was free of FMD:

Based on an evaluation of the 11 factors and observations from the site visit, APHIS considers that the Republic of Korea has the legal framework, animal health infrastructure, disease detection capabilities, reporting systems, and emergency response systems that are necessary for maintaining the Republic of Korea as free of FMD.¹

On December 28, 2009, APHIS issued a final rule declaring South Korea free of FMD and eligible to export fresh (chilled or frozen) beef to the United States beginning January 12, 2010. *See* 74 Fed. Reg., 68478, col. 3; 479, col. 2.

However, on January 6, 2010, just days before the effective date of APHIS' final rule, South Korea had an outbreak of FMD and APHIS was forced to delay indefinitely the effective date of South Korea's FMD-free designation. *See* 75 Fed. Reg., 1697, col. 1.

APHIS was dead wrong and the reality is that South Korea was unable to effectively contain the widespread FMD outbreaks that began Jan. 6, 2010 – outbreaks APHIS concluded were unlikely to occur. The South Korean FMD outbreak devastated South Korea's livestock industry.

5. APHIS' Risk Evaluation Methodology Resulted in the Miscalculation of FMD Risks in Japan

Nine years after APHIS declared Japan free of FMD, based exclusively on OIE standards (*see* 66 Fed. Reg., at 46228, col. 3, *supra*), APHIS was forced to take emergency action to ban beef imports from Japan due to numerous outbreaks of FMD that began in that country in April 2010.² On June 9, 2010, Bloomberg News reported that Japan had discovered 185,999 cases of

¹ APHIS Evaluation of the Status of the Republic of Korea Regarding Foot-and-Mouth Disease and Rinderpest, USDA-APHIS, October 2008, at 39.

² *See* U.S. Bans Japan Beef Imports Over FMD Concerns, USAgNet, May 21, 2010 (Reporting that Bloomberg news received an e-mailed statement from USDA regarding the imposition of a U.S. ban on Japanese beef imports), available at <http://www.wisconsinagconnection.com/story-national.php?Id=1027&yr=2010>

FMD and had destroyed 154,000 animals, with plans to destroy an additional 122,000 animals in its attempt to control the ongoing spread of FMD.³

The foregoing examples are all near misses and represent situations in which APHIS' actions threatened the health and welfare of U.S. livestock and U.S. livestock producers. As a result of APHIS' foregoing actions, the U.S. was particularly vulnerable to the importation into the United States of products that are known to carry the FMD virus and the importation of such products could have, as likely as not, resulted in widespread outbreaks of FMD in the U.S. livestock herd.

B. APHIS' Proposed Rule Is Inconsistent with USDA's Congressional Mandate to Protect Against the Introduction and Spread of Animal Diseases and Pests

The U.S. Animal Health Protection Act (AHPA) charges USDA with protecting the American people and the U.S. cattle herd from FMD. Congress was clear that "the prevention, detection, control, and eradication of diseases and pests of animals are essential to protect . . . animal health [and] the health and welfare of the people of the United States." 7 U.S.C. § 8301(1). In order to provide this protection, the AHPA authorizes the Secretary of Agriculture to "prohibit or restrict . . . the importation or entry" of cattle or beef "if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock." *Id.* at § 8303 (a)(3).

APHIS previously promulgated a rule to regionalize Santa Catarina, Brazil. In that rulemaking, APHIS acknowledged its actions would increase the United States' current risk for FMD, in contradiction of APHIS' statutory obligations. APHIS emphatically stated:

Although the required mitigations of the preferred alternative [the regionalization of Brazil] have been shown to be effective against all known strains of the viruses causing these five diseases [including FMD] there remains some potential risk that does not exist under the no action alternative [the action of not regionalizing Brazil]." Emphasis added.⁴

C. Conclusion

The foregoing examples of near misses, coupled with APHIS' previous admission that its regionalization scheme increases the United States' risk of FMD introduction, demonstrates that APHIS's proposed regionalization rule for Brazil undermines APHIS' statutory duty and, that APHIS lacks both the ability and capacity to accurately assess the level of risk for FMD presented by countries with histories of FMD outbreaks, including countries where FMD had not been reported for nearly a decade, e.g., Japan and South Korea.

³ See Japan Sees 'High Risk' of Foot-And-Mouth Expansion (Update 1), Bloomberg, June 9, 2010, available at <http://www.businessweek.com/news/2010-06-09/japan-sees-high-risk-of-foot-and-mouth-expansion-update1-.html>.

⁴ Proposed Rule for the Status of Santa Catarina, Brazil, Regarding Foot and Mouth Disease, Classical Swine Fever, Swine Vesicular Disease, African Swine Fever, and Rinderpest, Environmental Assessment (hereafter "Brazil Environmental Assessment"), January 2010, U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), at 6.