

Fighting for the U.S. Cattle Producer!



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October 8, 2010

Docket No. APHIS-2010-0011
Regulatory Analysis and Development,
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238.

Via E-Mail: www.regulations.gov

Re: R-CALF USA Comments in Docket No. APHIS-2010-0011: Availability of an Environmental Assessment for Field Testing Foot-and-Mouth Disease Vaccine, Live Adenovirus Vector

Dear Sir or Madam:

The Ranchers-Cattlemen Action Legal Fund, United Stockgrowers of America (“R-CALF USA”) appreciates this opportunity to submit comments to the U.S. Department of Agriculture (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) regarding the agency’s notice: *Availability of an Environmental Assessment for Field Testing Foot-and-Mouth Disease Vaccine, Live Adenovirus Vector* (“the Notice”) published at 75 Fed. Reg., 54589-590.

The Notice and accompanying documentation state APHIS intends to authorize shipments of an unlicensed foot-and-mouth disease (“FMD”) vaccine, live adenovirus vector (“experimental FMD vaccine”), for field testing on approximately 600 U.S. cattle in the states of Nebraska, Missouri, and Michigan, “unless substantial issues bearing on the effects of this action are brought to our [APHIS’] attention.”¹

Further, both the Notice and accompanying Environmental Assessment (“EA”)² state unequivocally that “APHIS has conducted a risk analysis”³ (emphasis added), and based on the risk analysis *APHIS conducted*, the agency “concluded that the safety risks to animals, public health, and the environment are low.”⁴ However, the only risk analysis provided by, and referenced by, APHIS in the Notice and in the EA is a risk analysis conducted by PerOs USA, Inc., under contract with GenVec, Inc., the very company that seeks APHIS approval for the proposed field test and for a U.S. Veterinary Biological Product license for the experimental

¹ 75 Fed. Reg., 54589, cols. 2,3.

² Environmental Assessment for Field Testing Foot-and-Mouth Disease Virus Vaccine, Live Adenovirus Vector (hereafter “EA.”).

³ 75 Fed. Reg., 54590, col. 1: *see also* EA, at 1.

⁴ EA, at 1.

FMD vaccine.⁵ This is, of course, contrary to APHIS' express statements contained in the Notice, as well as APHIS' express reference to the risk analysis as its own: APHIS states, "Based upon the results of our risk analysis . . ."⁶ (emphasis added.).

Based on the totality of public information APHIS provided at the Federal Web site: www.regulations.gov, in Docket No. APHIS-2010-0011, a risk analysis conducted by APHIS, or by any independent, non-pecuniary vested scientific research entity under contract with APHIS, has not been completed regarding the risks of testing the experimental FMD vaccine. R-CALF USA believes this fundamental deficiency is substantial as it prevents an unbiased, independent determination regarding the actual risks associated with the field tests proposed in the Notice. For this reason, APHIS should withdraw the Notice, conduct an independent analysis of the potential risks of conducting field tests on the experimental FMD vaccine, and prepare an environmental impact statement before the commencement of any such tests.

APHIS states that the safety risks associated with the proposed field tests of the experimental FMD vaccine are low for animals, public health, and the environment.⁷ It additionally states that: 1) "[t]he likelihood of recombination occurring in the field with an undetected live FMD virus is very low;"⁸ 2) "[t]he potential for escape and dispersal of this recombinant vaccine is low;"⁹ 3) the likelihood of virulence and survivability of the vaccine virus in any host is negligible;¹⁰ and, 4) it is "unlikely an exchange of genetic material with wildtype FMDV would occur."¹¹

APHIS has a long history of declaring risk events "unlikely" and safety risks "low," "very low," "negligible," and "extremely low" without any quantifiable evidence and even in the face of empirical evidence that proves the opposite. For example, in 2005 APHIS stated with respect to Canada's ongoing bovine spongiform encephalopathy ("BSE") outbreak that ". . . measures currently in place in Canada . . . make it unlikely that new cases are developing."¹² And, ". . . animals born after the feed ban was implemented are unlikely to have been exposed to the infectious agent."¹³ However, since 2005, Canada has detected 14 new BSE-infected cattle under Canada's extremely limited and voluntary testing program, and 11 of these infected animals were born *after* Canada's feed ban.

APHIS further made the following overly optimistic prediction after the detection of the first two BSE-infected native cows in Canada: "[T]he likelihood of the spread and establishment of BSE in Canada, both before and after the 1997 feed ban, was negligible."¹⁴ Empirical evidence, however, proves APHIS' optimistic assumption false, as BSE cases in Canada have

⁵ See EA, at 1; *see also* 75 Fed. Reg., 54589, col. 3.

⁶ EA, at 5.

⁷ See EA, at 1.

⁸ EA at 3.

⁹ *Id.* at 4.

¹⁰ See *id.*, at 4

¹¹ *Id.* at 4.

¹² 70 Federal Register, at 528.

¹³ 70 Federal Register, at 485.

¹⁴ 70 Federal Register, at 468.

become manifest both long before and long after the feed ban, with the birth dates of infected cattle spanning over a 14-year period, and the locations of the infected cattle span over 3 Canadian Provinces.

Although APHIS stated there would not be continuing exposure to BSE, nor infection, of Canadian cattle after the 1997 Canadian feed ban, APHIS' risk analysis explicitly stated that the discovery of such cattle would indicate that the feed ban was not effective as APHIS assumed.¹⁵ However, even after Canadian cattle born after, and therefore infected after, the 1997 Canadian feed ban were detected with BSE, APHIS continued to assert that the 1997 Canadian feed ban was effective, thus allowing Canada to continue to meet the requirements for a BSE "minimal risk" country even though it no longer met the requirement for having "[a] ruminant-to-ruminant feed ban that is in place and is effectively enforced."¹⁶

More recently, APHIS unequivocally asserted that because of the "extremely low likelihood" that cattle born in Canada on or after March 1, 1999, will have been exposed to BSE,¹⁷ the agency's over-thirty-month rule ("OTM Rule") ensures that the BSE risk to the United States from the import of OTM cattle remains "negligible."¹⁸ Yet, Canada already has detected 11 cases of BSE in native cattle born after March 1, 1999, under Canada's extremely limited and voluntary BSE testing program.

This prolonged, historical evidence of APHIS' political advocacy, which stands in stark contrast to the agency's scientific responsibilities, has destroyed APHIS' credibility and has rendered APHIS' non-quantitative and non-independently substantiated conclusions regarding risks not just suspect, but unbelievable. Moreover, APHIS' actions have reduced and continue to reduce demand for U.S. beef, as particularly evidenced by the numerous beef export markets that, since late 2003, continue to impose severe restrictions on U.S. beef exports.

For this additional reason, R-CALF USA recommends that APHIS withdraw its proposal to approve the testing of the experimental FMD vaccine and conduct a thorough, quantitative analysis of the potential safety risks associated with the Notice so the public can determine whether APHIS' conclusions regarding safety risks are scientifically based or politically motivated.

As a final concern, R-CALF USA urges APHIS to consider another alternative other than that disclosed in the EA. APHIS should not risk conducting tests for FMD vaccines in the United States where FMD does not exist. It would be far more prudent for APHIS to conduct live animal tests in one of the 70 countries where FMD is endemic and where wildlife, including deer, small

¹⁵ See Analysis of Risk – Update for the Final Rule: Bovine Spongiform Encephalopathy; Minimal Risk Regions and Importation of Commodities, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, December 2004, at AR008322; see also Declaration of William D. Hueston, Guy H. Loneragan, and Srinand Sreevatsan, *R-CALF USA v USDA*, June 7, 2005, attached hereto as Attachment D, at 24, 25.

¹⁶ 70 Fed. Reg., 550, col. 1; see also, 72 Fed. Reg., 1106, cols. 1,2.

¹⁷ 72 Fed. Reg., 53329, col. 3.

¹⁸ *Id.*, at 53316, col. 1.

animals, and birds, would already be subjected to the disease. It is noted within the Summary Information Format and Risk Assessment conducted by PerOS USA, Inc., that: 1) the rate of replication-competent adenovirus generation has not been determined;¹⁹ 2) the amount of investigational veterinary product shed from vaccinates was determined only to be not “in sufficient amounts to cause production of Ad5-specific vaccine vector antibody in contact exposed cattle;”²⁰ 3) the regulated biological agent (“RBA”) was recovered after the first 24 hours post inoculation from 4 of the 10 animals to which it had been administered;²¹ 4) while the RBA was determined by PerOS USA, Inc., not to be virulent for targeted animals, i.e., domestic livestock, the company did reach the same favorable conclusion for wildlife – it states that the RBA was not “anticipated to be virulent for non-targeted animals;”²² and, 5) PerOS USA, Inc., did not rule out completely the probability that replication deficient human adenovirus RBA could co-infect a cattle cell.²³

The equivocal nature of the evidence discussed above suggests that APHIS should conduct tests for FMD viruses only in countries where the disease already exists and where an inadvertent error by researchers, or a miscalculation of risks, would not harm independent U.S. livestock producers.

For the reasons set forth above R-CALF USA urges APHIS to: 1) abandon its proposal to field test the experimental FMD vaccine; 2) conduct testing of the experimental FMD vaccine only in countries where the disease already exists; and, 3) to at least conduct its own, independent risk assessment that includes a quantitative analysis of risks and a completed environmental impact statement before resubmitting its proposal to the public. R-CALF USA believes the issues it has brought to APHIS’ attention herein are substantial and warrant APHIS’ abandonment of its proposal.

Sincerely,



R.M. (Max) Thornsberry, D.V.M.

R-CALF USA President of the Board

¹⁹ See Confidential Business Information-Deleted Risk Analysis Consisting of The Summary Information Format & Risk Assessment for Foot and Mouth Disease Virus Vaccine, Live Adenovirus Vector, PerOs USA Inc. (under contract with GenVec, Inc.), April 3, 2009 (hereafter “SIF”), at 8.

²⁰ *Id.* at 10.

²¹ *See id.*, at 18.

²² *Id.*, at 21.

²³ *See id.*, at 23.