



EQUINE INFECTIOUS ANEMIA (EIA)

Concept for Federal Regulations

Purpose

The Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) would like to assess the level of stakeholder support for the publication of an EIA proposed rule and we are seeking feedback on the regulatory concepts for EIA control presented here.

Background

EIA virus infection of equids has a worldwide distribution, can produce severe disease or death, and can occur as a lifelong subclinical carrier state. The disease is transmitted via biting arthropods and iatrogenic means (i.e. unhygienic practices such as needle sharing). No vaccine is currently approved for use. The insidious and subclinical nature of EIA infection means infected animals are not recognized or removed from the population, and as a result can silently pass the disease to nearby horses. Most EIA reactors are humanely destroyed, although the option for lifelong quarantine does exist in some States. The disease and efforts to control it result in significant costs. EIA testing in the United States was estimated to cost the equine industry approximately \$37 million in 2015.¹

Reliable diagnostic testing for EIA was developed over 40 years ago, with State and Federal cooperative control efforts beginning soon afterward. These largely State-based EIA control efforts have been very successful. Between 1972 and 2015, the rate of reactors among the tested population declined from 3.8 percent to 0.005 percent; however, the decline has plateaued in recent years. Recent clusters of cases have demonstrated how quickly and widely the disease can spread.²

Since 2013, at least 66 cases of EIA in Quarter Horse racehorses have been identified in eight States, with epidemiological evidence of iatrogenic transmission in all cases. This has raised concerns about the adequacy of current measures. The subclinical nature of the disease and the frequent repurposing of these racing animals for other uses raise the risk of further outbreaks of EIA. Some States lack adequate resources or equine expertise to adequately control equine disease outbreaks.³ Positive animals have increasingly been reported in States that have not found disease cases for many years.⁴ Additionally, horses for slaughter may not be required to have a current EIA test. The lack of equine slaughter plants in the United States means untested horses may cross the Nation before being exported to Mexico and Canada. Current control efforts appear to have reached their logical limit. Given the low prevalence, further reductions will only come with changes in how we conduct surveillance and control.

Existing EIA Regulations

The States currently regulate most aspects of EIA control in the United States. State regulations vary, with testing intervals for entry into States ranging from 2 months to 12 months. Federal regulations and associated policy documents are limited to movement restrictions of EIA reactors and the approval of EIA testing laboratories. There are no uniform interstate movement requirements, nor is there a regulatory framework for a federally-coordinated EIA control program. This lack of national coordination impairs VS' ability to implement certain risk-based surveillance and control measures and to prosecute veterinarians for EIA-related accreditation violations.

Support for Federal EIA Regulations

Over the last 10 years, the U.S. Animal Health Association (USAHA) and National Institute for Animal Agriculture have passed eight resolutions or recommendations supporting the strengthening of Federal EIA regulations or improved disease control. VS drafted a proposed EIA rule in 2012; however, the proposed rule was not published due to a perceived lack of stakeholder support and because APHIS wanted to explore nonregulatory solutions. VS convened an EIA Discussion Group of State, Federal, and industry representatives in 2015. The group was asked to examine current EIA strategies and regulations, identify gaps, and propose nonregulatory and regulatory options. There was considerable enthusiasm among group members to strengthen EIA control efforts, building on a foundation of Federal regulations. Further, group members expressed concerns that limited Federal authority, variable State regulations, and inconsistent enforcement have resulted in confusion, misinformation, and opportunities for avoiding regulations or fraud. They recognized that while EIA test documentation has not impeded our control of the disease, EIA test forms are nonetheless a very important form of equine identification. These forms serve regulatory officials as a valuable traceability tool, and the current lack of uniformity in these forms is problematic. A summary of the EIA Discussion Group is available on the VS website: <http://www.aphis.usda.gov/animal-health/equine-health-eia>. Subsequent to the EIA Discussion Group, and in light of changing disease risks, several prominent equine industry groups asked to consider a proposed EIA rule or other control options.

Proposed Rule for EIA Control

In light of this feedback, VS is again considering publishing a proposed rule for EIA control. The proposed rule would be performance-based to allow for flexibility in implementation. Putting compliance details in a Program Standards document will allow for changes without rulemaking or amending the CFR. The proposed rule would:

- Require a standard (12 month) EIA testing interval for all equine in interstate transit;
- Require use of the VS 10-11 test form or VS approved alternate forms that contain identical data fields;
- Require USDA Category II accreditation of veterinarians submitting samples;
- Require submission of all non-negative samples to National Veterinary Services Laboratories (NVSL);
- Centralize laboratory result and monthly data reporting to VS (and States);
- Clarify and standardize laboratory approval requirements; and
- Further define exposed equines to include epidemiological connections.

This regulation would take the important step of codifying existing EIA control practices, provide Federal authority to aid in enforcement, and provide comprehensive national standards for the control and prevention of EIA. The proposed rule would lay the regulatory ground work and have the performance-based flexibility for future control options in the face of any needed changes based on future epidemiology, newly developed diagnostic tests, or altered disease status. As conceived, this proposed rule would negate certain interstate agreements allowing exemptions to testing and would supersede some State regulations with a more frequent testing interval.

In addition to this proposed regulatory approach, VS is also considering the following nonregulatory solutions to compliment the proposed EIA rule and strengthen EIA control:

1. Use existing authorities and guidance to increase oversight and compliance.
 - a. Issue a revision to VS Memo 555.16 as VS Guidance Document 15201.1 “Approval of EIA Testing Laboratories.”
 - b. Develop and disseminate clear guidance and invigorate compliance activities for EIA control.
2. Facilitate and encourage risk-based, targeted surveillance.
 - a. Analyze the additional data that will be acquired from the approved EIA laboratories, conduct modelling and prevalence surveys for risk analysis/targeting, and share summary reports with States and Tribes.
 - b. Encourage States and Tribes to use these data to conduct risk-based surveillance.
3. Encourage and conduct broad-based education and outreach using cooperating partners, including the Equine Disease Communication Center, State officials, American Association of Equine Practitioners, breed and sport organizations, Equine Forum, agricultural curricula, and extension channels.

Please provide your feedback on the concepts in this document by

December 31, 2016 to:

vs.sprs.equine.health@aphis.usda.gov .

- (1) 1.35 million EIA tests were performed in 2015, which when multiplied times the average cost of EIA test to the owner from the estimate provided in the 2005 NAHMS study (Part I report, page 30) of \$27.33 results in an annual cost of EIA testing to the industry of \$37 million annually. This figure is exclusive of State or Federal support for laboratories, testing, reporting, or epidemiology.
- (2) <http://www.usaha.org/Portals/6/Reports/2014/report-hd-2014.pdf>
- (3) <http://www.animalagriculture.org/resources/Documents/Conf%20-%20Symp/Symposiums/2016%20Equine/Equine%20Diseases%20Forum%20Whitepaper%20PDF%2006.08.16.pdf> page 20
- (4) https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/horse-disease-information/equine-infectious-anemia/ct_eia_distribution_maps