



EQUINE INFECTIOUS ANEMIA (EIA)

DISCUSSION GROUP 2015

Veterinary Services (VS); Animal and Plant Health Inspection Service (APHIS);
U.S. Department of Agriculture (USDA)

Executive Summary

The U.S. equine industry is a \$40 billion enterprise with an estimated \$104 billion of indirect economic impact. (1) The United States is the world leader in the value of exported horses, with live horse exports approaching \$500 million per year, exceeding the corresponding value of all other U.S. live animals combined (cattle, sheep, pork, and goats). (2)

EIA virus infection has a worldwide distribution. It can produce severe disease or death in equids and can also occur as a lifelong infection with a subclinical carrier state. The disease and efforts to control it result in significant costs related to interstate movement, commerce, and international trade. EIA testing in the United States was estimated to cost the equine industry approximately \$38 million in 2014. (3)

State and Federal cooperative control efforts for EIA began in the United States soon after reliable diagnostic testing was developed over 40 years ago. Federal regulations are confined to movement restrictions of EIA reactors and the approval of EIA testing laboratories. States currently regulate most aspects of EIA control in the United States; however, State regulations vary. EIA control efforts have been very successful; between 1972 and 2014 the rate of reactors among the tested population declined from 3.8 percent to 0.00004 percent. Control efforts appear to have reached their logical limit, which means that given current levels of extremely low prevalence, further reductions will only come with extensive changes in how we conduct surveillance and control.

VS convened the EIA Discussion Group in 2015 in an effort to determine the way forward. The group was composed of State, Federal, and industry representatives, and it was tasked with discussing goals for addressing EIA in the United States, examining current EIA strategies and regulations, identifying gaps, and proposing nonregulatory and regulatory options (or both) to address gaps and achieve goals. The purpose of the group was to obtain information and viewpoints from individual attendees. This group could not provide a collective recommendation or consensus statement since it was not an official Federal Advisory Committee.

This discussion group addressed several areas related to management of EIA in the United States, including:

- Goals and Scope for EIA Control;
- ID and Documentation;
- Surveillance Strategies;
- Testing & Diagnostics;

- Stakeholder Support; and
- Alternatives to Regulation.

Key observations of the discussion group included the following:

- There was considerable enthusiasm among many group members to strengthen EIA control efforts to capitalize on existing successes.
- Many group members believed that the goal should be EIA eradication; however, they expressed concerns about the feasibility and ability to fully achieve this goal.
- Several group members felt that the foundation of any increased EIA control or eradication effort should include Federal regulations.
- Although there is room for improvement, current equine identification and documentation of EIA test status are not viewed as barriers to EIA control.
- Reservoirs of infection exist in untested animals in the United States, and targeted surveillance in these populations is needed. Stray animals and illegal movement of animals or blood products from Mexico may serve as potential sources of infection.
- Several group members supported a targeted approach to both surveillance and disease control. Members proposed a State-level status or regionalization as options to target resources and EIA control activities.
- Current EIA testing paradigms are sufficient for control of the disease.
- Limited Federal authority, variable State regulations, and inconsistent enforcement have resulted in confusion, misinformation, and opportunities for avoiding regulations or fraud.
- Some group members viewed industry support as lacking, and some hoped an education campaign would build industry support. Broad support would be necessary to successfully increase efforts for EIA control or implement eradication.
- New, cooperative funding streams from Federal, State, and industry sources will be required to proceed with any enhanced control or eradication efforts.

EIA Regulations

EIA virus infection 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, and no vaccine is currently approved for use. Most EIA reactors are humanely destroyed without Federal indemnity offered, but there are options for lifelong quarantine.

State and Federal cooperative control efforts for EIA began in the United States soon after reliable diagnostic testing was developed over 40 years ago. EIA control efforts have been very successful; between 1972 and 2014, the rate of reactors among the tested population declined from 3.8 percent to 0.00004 percent. However, reservoirs of infected equids remain among the untested population. A 2005 National Animal Health Monitoring System (NAHMS) study suggested that only 35 percent of the U.S. equine population was being tested. Recent clusters of cases among unsanctioned racing Quarter Horses, spread by iatrogenic means, have demonstrated how quickly the disease can spread and raised concerns about the adequacy of current measures. Current control efforts appear to have reached their logical limits.

Federal regulations and associated policy documents are confined to movement restrictions of EIA reactors and the approval of EIA testing laboratories, as listed below. As a result, we lack the regulatory

framework for a federally coordinated EIA control program, which impacts our ability to implement certain risk-based surveillance and eradication/control measures and to pursue enforcement actions against veterinarians for EIA-related accreditation violations.

Code of Federal Regulations (CFR) addressing EIA:

- Restriction on interstate movement and disposition of EIA reactors – 9 CFR 75.4
- Approval of Laboratories, and Diagnostic or Research Facilities. – 9 CFR 75.4
- Testing requirement for equines imported into the U.S.A. – 9 CFR 93.308

VS Guidance Documents addressing EIA:

- 2007 Uniform Methods and Rules EIA guidance document
- VS Memo 555.7 “Approval of EIA Research Facilities”
- VS Memo 555.16 “Approval of EIA Testing Laboratories” (to be reissued as VS Guidance Document 15201.1 later in 2015)

Given the lack of existing Federal regulations, State Animal Health Officials (SAHOs) currently regulate most aspects of EIA control in the United States; however, State regulations vary. Some States have requirements to test only for interstate movement, others test upon transfer of ownership, some require testing for event participation and, in some States, all horses commercially housed are required to be tested for EIA. Testing intervals also vary across States and range from every 6 months to every 2 years. In addition to State requirements, racing authorities, show venues, stables, and other organizations may require EIA testing.

Over the last 10 years, eight U.S. Animal Health Association (USAHA) and National Institute for Animal Agriculture resolutions or recommendations have supported strengthening Federal EIA regulations or suggested other ways to improve disease control. In general, strengthened regulations enjoy considerable support among SAHOs; however, industry has been more ambivalent or divided in their opinion. Some prominent industry groups have recently indicated a willingness to reevaluate their position on EIA control in light of changing disease risks.

VS drafted a proposed EIA rule in 2012. The intent of the proposed rule was to provide comprehensive and effective national standards for the control and prevention of equine infectious anemia...and to lay the regulatory ground work for control options in the face of changes in science, testing or disease status. However, the proposed rule was not published due to a perceived lack of strong stakeholder support. In 2014, VS suspended further action on the draft proposed rule and committed to re-evaluating the need for rule. This is in line with APHIS' standard practice of considering nonregulatory solutions to animal health problems based on risk assessments and sound science before promulgating new regulations.

EIA Discussion Group

VS convened the EIA Discussion Group in 2015 in an effort to determine the way forward. A USAHA Infectious Disease of Horses Committee (IDOHC) resolution in 2014 supported the group's formation. The EIA Discussion Group was asked to discuss the goals for addressing EIA in the United States, examine current EIA strategies and regulations, identify gaps, and propose nonregulatory and regulatory options (or both) to address gaps and to achieve goals.

The Discussion Group was composed of State, Federal, and industry representatives to solicit input from a wide range of internal and external stakeholders. Invited members of the Discussion Group included five SAHOs, two American Association of Equine Practitioners representatives, two (rotating) American Horse Council representatives, a university (EIA) researcher, a commercial shipper, a commercial laboratory representative, and three VS Assistant Directors.

The purpose of the group was to obtain information and viewpoints from individual attendees. The group could not provide a collective recommendation or consensus statement since it was not an official Federal Advisory Committee.

The group members participated in eight conference calls from April to July 2015, and members discussed the following topics:

1. Goals and Scope for EIA Control;
2. ID and Documentation;
3. Surveillance Strategies;
4. Testing and Diagnostics;
5. Stakeholder Support; and
6. Alternatives to Regulation.

Summary of Comments

1. Goals & Scope for EIA Control

Discussion Summary:

The Discussion Group considered “three options” for EIA control:

- 1) discontinue EIA control efforts;
- 2) continue or enhance EIA control efforts; and
- 3) eradicate EIA from the United States.

These options represented the complete spectrum of possible goals for EIA response.

Members immediately expressed concerns over the inclusion of the option to end EIA control measures. Some members felt so strongly that they did not even want to discuss the option to discontinue control efforts for fear of giving the idea credibility. VS facilitators assured the group that these options were not intended to signal a preferred approach by VS. Further, exploring the option for discontinuing EIA control efforts would provide an opportunity to determine a baseline for a cost versus benefit analysis.

A wide range of participants voiced considerable support for eradication of EIA. Group members viewed eradication as the preferred goal. One member stated that current disease management efforts should be brought to their logical conclusion – eradication – to avoid wasting the considerable efforts and resources already invested toward control. However, members acknowledged it would be difficult to implement and it may not be feasible to achieve eradication considering funding constraints. No members expressed strong opinions against an eradication effort.

Given funding limitations and implementation challenges for eradication, group members agreed that strengthening existing control measures was a reasonable near-term option for future management of EIA. One member's point of view was that current control efforts have been so successful that we should declare the majority of the United States to be free of EIA and begin "mop up" activities. Others noted that this is an accurate description of our status by most disease control standards.

Some members stated that industry would not fund enhanced control efforts, and that funding should be solicited from USDA. The funding strategy should take into account reductions in industry testing costs that would be realized with a risk-based control plan.

2. ID and Documentation

Current Status:

Federal identification requirements for EIA control only refer to reactors and state that reactors should be permanently identified by application of a hot iron or chemical brand, freeze marking, or a lip tattoo. They further refer to recording the reactor's age, breed, color, sex, and distinctive markings when present (such as brands, tattoos, scars, or blemishes). VS EIA guidance documents mention identification with regard to sample submission to approved EIA laboratories and reference name, age, breed, sex, color, markings, and tattoo or breed registration number.

There are no Federal regulations specific to documentation of EIA testing. VS guidance documents do not require an official or standard test form. Instead, they specify an "individual animal identification form" that includes certain laboratory and owner information, dates, identification of the animal, and unique accession number.

The VS 10-11 and its electronic version is an official EIA test form, although its use is not required. There are also various State EIA test forms in use and some commercial companies offer electronic versions of EIA test forms along with form management services. EIA test forms typically include name, age, breed, sex, color, and markings as written descriptions. Some forms include an equine silhouette for drawing detailed descriptions, and some include provisions for electronic photographs to be attached to the document.

Discussion Summary:

Multiple group members emphasized that equine identification and documentation was not a limiting factor for successful implementation of current or past EIA control efforts or for successfully conducting most epidemiological investigations. While it was clear there remains room for considerable improvement in our methods for identifying horses, group members felt that this topic was a distraction from the group's purpose and it was best discussed in another venue.

Group members made it clear that the lack of uniformity of EIA test forms across States results in confusion and problems with acceptance of the various forms. They discussed concerns about fraudulent sample submissions and documentation, and some members felt there was rampant abuse.

Importantly, many group members emphasized that EIA test forms are commonly used and generally accepted as the only required form of equine identification. These forms are recognized as a valuable method of identification especially when horse markings are hand-drawn in detail. Some States pointed out that the documentation associated with EIA control activities helps regulatory officials with the

overall traceability of horses. They expressed concerns that the elimination of or decrease in EIA testing in certain geographic areas could further reduce the minimal traceability currently in place.

The group focused considerable discussion on the advantages and limitations of digital forms and photographs and specifically cited a lack of uniform standards for these electronic formats. Several members indicated that the use of digital photographs has led to challenges in identification due to poor quality photographs. Additionally, they believe that digital test forms have the potential for fraud when they are electronically reproduced.

Many group members believe that the gold standard for future traceability in equines is individual microchips and a central repository of data. However, the burden of ensuring chip reader availability may be a logistical challenge. Multiple parties expressed support for use/retention of hand signed and filled out paper 10-11s. Unrelated to the EIA control discussion, several members requested that APHIS require imported horses have a microchip and that APHIS maintain a database containing this information for identification and traceability.

Identification and documentation, as they exist, are sufficient to carry out a successful EIA Control program.

3. Surveillance Strategies

Current Status:

In the United States, EIA surveillance efforts have concentrated on equids that move frequently or are otherwise visible and available for testing. The availability of relatively inexpensive blood test(s) using very reliable diagnostics in an easily accessible population of animals has largely controlled the disease in that population.

However, reservoirs of infection are presumed to remain in subpopulations of equids that do not move off of their resident premises or other groups of animals that are not tested. Several established sales and movement traditions occur with limited regulatory oversight. The lack of equine slaughter plants in the United States means significant numbers of market horses move great distances nationwide before subsequent export to Mexico and Canada, sometimes exploiting regulatory confusion to circumvent EIA testing. According to 2014 World Organization for Animal Health (OIE) reporting, EIA is present in Mexico, creating a possible source of infection for U.S. equids through illegal movements of animals or blood products and movement of stray animals across the border. Epidemiological investigations of several recent cases of EIA in the western United States have identified iatrogenic transmission of infection resulting from unhygienic injection practices and “blood doping” in unsanctioned racing circuits. These horses are serving as previously unrecognized or underappreciated reservoirs of infection. This is particularly concerning because the subclinical nature of the disease and the frequent repurposing of these racing animals for other uses allows the infection to persist and raises the risk of further outbreaks of EIA as these animals come in contact with other populations of equids.

APHIS is currently updating its EIA prevalence model at the USAHA’s request. This will be a useful tool for further evaluating existing EIA surveillance and identifying surveillance gaps.

Discussion Summary:

The group observed that the targeted population was over tested. Members generally felt that some type of risk-based surveillance plan would be appropriate for EIA. The goal would be to target the previously untested reservoirs of infection and to increase surveillance in these populations. It was suggested that one such surveillance target may be various populations of free-roaming animals on Federal lands; however, group members anticipated that identifying and testing other privately owned populations would present some hurdles. Producers may not cooperate with a surveillance program that would likely result in death or total loss of value of their animals. The group recommended that an educational campaign is essential and regulatory authority will be necessary to successfully implement this type of surveillance.

The group spent considerable time discussing the use of incentives to increase access to populations with little or no testing history. However, they were concerned that such incentives may not be effective given the reality that reactors will likely be destroyed. Participants felt indemnity for infected animals was worthy of consideration as a means to enhance surveillance. They commented that existing control efforts result in a de facto test and slaughter program with no indemnity offered. This may be a disincentive for transparency and willingness to participate in testing and should be considered while designing a surveillance strategy. Several members voiced concerns about developing a surveillance strategy when industry does not appear to see EIA as a funding priority.

Several members referred to an “enhanced EIA control plan” or “Five State Plan” that was discussed by the USAHA IDOHC as early as 2007. Some observed this approach primarily benefited States in the “free” areas, but may negatively affect States in the “affected” areas. VS participants viewed the lack of support for this concept in the past as primarily due to resistance to increased testing in these areas. Other members suggested using a more traditional State-by-State designation for EIA status, similar to what is used for brucellosis. Under this model, the EIA-free or low-incidence States would have decreased testing requirements, perhaps every 2 years. It was suggested that States affected by EIA will support increased testing in their populations. Some States have requirements to test all animals on a periodic basis. One member noted that Canada appears to be considering an east/west regionalization approach to EIA control, and he shared a summary of Canada’s proposed approach with the group.

Finally, there was overwhelming support among members for an in-person meeting to advance an enhanced EIA Control Program or an Eradication EIA Program. It was felt this would be a more effective and broader forum for advancing work on a surveillance strategy, as opposed to the current conference call format.

4. Testing and Diagnostics

Current Status:

Federal authority in the CFR applies to movement and disposition of EIA reactors and to authorization for VS to approve EIA testing laboratories. Operational details are described in VS Memorandum 555.16, Approval of Laboratories to Conduct Tests for Equine Infectious Anemia. Laboratory approval is a cooperative process between SAHOs and VS, and includes a formal application, a compliance agreement, periodic inspections, and training of persons conducting the EIA test by the National Veterinary Services Laboratories (NVSL).

Approved EIA laboratories are required to use ELISA or AGID kits licensed by the APHIS Center for Veterinary Biologics for EIA testing. Laboratories choose which test or tests to conduct (some States mandate test type). Laboratories are required to send samples with discrepant EIA results to NVSL for confirmatory testing. State, Federal, or university laboratories must confirm samples with positive ELISA results using the AGID. The NVSL does not conduct commercial EIA testing. Rather, it serves as the national reference laboratory for EIA and is one of three OIE reference laboratories for EIA worldwide.

There are 465 approved EIA testing labs in the United States that perform commercial EIA testing. Some States have almost 100 commercial EIA testing laboratories, while others have one or two.

VS plans to issue a revision to VS Memo 555.16 in the near future as VS Guidance Document 15201.1. The revision will:

- Require that all non-negative (positive, discrepant, suspect, or equivocal) samples be confirmed at NVSL.
- Define and require the use of official test forms.
- Enhance inspection requirements, revise inspection checklist.
- Increase emphasis on reporting requirements and providing summary data.
- Clarify approval requirements and remove references to economic needs for lab approval.

Discussion Summary:

Group members did not perceive a need to make any major changes to the existing U.S. EIA test method protocols. The group considered the current protocols to be sufficient for control measures, as evidenced by the success of current efforts.

The group discussed a 3 tier testing protocol:

- 1st tier—Commercial laboratories use USDA-licensed ELISA test kits as an initial screening test because of their high sensitivity.
- 2nd tier – State Veterinary Diagnostic Laboratories confirm positive ELISA results with the AGID test (Coggins test).
- 3rd tier – NVSL performs final confirmatory testing and uses the Western Blot or other tests.

The group discussed advantages to the three-tier testing protocol, but wondered if it could be required and implemented without a regulatory framework. The group recalled that the three-tier protocol did not receive wide acceptance when it was first proposed several years ago.

Once VS Guidance Document 15201.1 is implemented, it will essentially create a modified two-tier system. ELISA and AGID tests will be performed at commercial and State labs with referral of all non-negative samples to NVSL for confirmatory testing. One SAHO expressed concerns about sending all non-negative samples to NVSL for confirmation, while others did not anticipate problems in doing so.

5. Stakeholder Support

Discussion Summary:

The insidious and subclinical nature of EIA infection allows it to avoid wide recognition. Many horses can carry the disease their entire lives and silently pass it on to their pasture mates without it being discovered. Existing EIA control efforts have made such significant progress in reducing prevalence that few horse owners or veterinary practitioners have ever seen cases of EIA and its consequences. Additionally, group members felt the equine industry is also largely unaware of the success of current control measures and even less informed of the possible benefits of any eradication plan. The group predicted that if the U.S. equine industry actively supported more aggressive control efforts they could save millions of dollars annually through the subsequent reduction in amount of EIA testing needed.

Several members made impassioned pleas to garner industry support, capitalize on the significant progress made to date, proceed with more aggressive control, and eradicate EIA in the United States. Group members acknowledged that it will be hard to enhance control efforts or complete eradication without the buy-in of equine industry. Other members suggested that industry is not opposed to EIA control efforts; they just want effective regulations, within a consistent framework.

An industry trade group representative commented that his organization considered a previous EIA proposal but felt that current efforts are working fine and that putting additional effort into control and eradication was not necessary. However, reducing current efforts would be a mistake.

One member expressed frustration in a perceived lack of action or funding by USDA, stating, "We can eradicate [EIA] in the United States with short-term specific funding to some States using risk based surveillance. With Federal and State funding and industry help we can finish the job. We are so close to eradication that we can't walk away. Equine industry should demand that we finish this." The member requested action on the part of the USDA.

Importantly, group members acknowledged that these discussions may be moot if Federal funding is not made available and industry is similarly not disposed to provide funds to support these activities.

Group members again suggested that stakeholders, regulators, laboratories and academia need to meet face-to-face to discuss the details of implementing an enhanced EIA control program.

6. Alternatives to Regulation

Current Status:

APHIS' standard practice is to systematically examine alternatives to rulemaking before promulgating new regulations. Where possible, APHIS can develop non-regulatory solutions to animal health problems based on risk assessments and sound science. When necessary, APHIS will undertake rulemaking with a focus on developing overarching, performance-based regulations. The development of a successful EIA strategy, potentially including both nonregulatory and regulatory components, will require support among a wide group of internal and external stakeholders.

Federal regulations are needed when a disease program's success is dependent on requirements that must be enforced by the Federal government. In the case of EIA:

- If APHIS, the States, and industry view the existing State entry requirements as adequate to control the disease to the extent necessary, then a Federal regulation is not needed.
- If, on the other hand, those State requirements are not sufficiently rigorous or they vary too much (making compliance poor and enforcement difficult), APHIS should consider promulgating regulations so that we can enforce uniform interstate movement requirements.

Discussion Summary:

Many group members felt that the foundation of any increased EIA control or eradication effort must include Federal regulations. Group members felt that limited Federal authority, variable State regulations, and inconsistent enforcement have resulted in confusion, misinformation, opportunities for avoiding regulations, and fraud. They also asked VS to better enforce existing guidance and regulations.

A number of group members made it clear that they supported proceeding with Federal rulemaking and/or wished to “put more teeth in the regulations.” A number of SAHOs stated that if Federal efforts were to cease, they would continue or increase State efforts to control EIA, but noted that the result would be chaotic, with inconsistent regulations and restrictions on movement and trade. States with highest prevalence of the disease would be left to address EIA control at the State-level.

During this discussion, members reiterated several concerns that they had previously expressed. They were worried that reduced testing requirements for EIA would reduce equine traceability, since the EIA test form is often the only document we have for this purpose. They restated concerns about fraudulent submissions/documents, and indicated that any less regulation would result in more loopholes.

Group members identified that the limited Federal authority with regard to accreditation violations, including proper use of test forms and sample submissions, will require a Federal regulatory approach.

Several members repeatedly requested to read and/or comment on the draft proposed EIA rule that was not previously published, or to have USDA propose another reasonable, pragmatic rule for comment.

Next Steps

VS will compile feedback from stakeholders on the ideas put forward by the Discussion Group. Based on comments and input received, the VS will formulate options and consider how to move forward.

References

(1) “Economic Impact of the Horse Industry on the US,” 2006, available at <http://www.horsecouncil.org/national-economic-impact-us-horse-industry>.

(2) Global Trade Atlas by Global Trade Information Services, 2012

(3) 1.4 million EIA tests run times the average cost of EIA test to the owner from the 2005 NAHMS study (Part I report, page 30) of \$27.33 equals approximately \$38 million in cost to the owner(s). This figure is exclusive of State or Federal support for laboratories, testing, reporting, or epidemiology.