National Horse Show Commission, Inc.

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Dr. Rachel Cezar
Horse Protection Coordinator
USDA/ APHIS Animal Care
4700 River Road, Suite 6D03
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Dear Dr. Cezar:

Thank you for USDA's recent responses to the HIO comments on the proposed foreign substance penalty. In reviewing those responses however, we would like some additional clarification on some of the points, and would like to further respond to others.

USDA issued a press release in April of 2006 in regards to the use of GC/MS which stated:

"The testing procedures and enforcement actions are as follows:

- APHIS veterinary medical officers will swab horses randomly at every sale or show they attend for the remainder of 2006.
- Swab tubes will be labeled by class and exhibitor number, and that information will be compared to the class sheets provided by show management or horse industry organization to determine the owner, custodian, trainer and exhibitor.
- Swabs will undergo testing at NVSL for the presence of foreign substances via mass spectrometry analysis.
- Any analysis that indicates the presence of a foreign substance will result in APHIS issuing an official warning letter, known as APHIS form 7060, signifying a violation of federal regulations to the owner, custodian and trainer of all affected horses, as well as exhibitor of the horse swabbed for samples taken "post show."
- A summary of the test results will be available on the HPA website at http://www.aphis.usda.gov/ac/hpainfo. html. The summary will name the show, its location (city and state), show date, the number of entries, the number of swabs done for analysis, the number of foreign substance(s) detected, the names of the foreign substance(s) detected, and the percentage of swabs that contained the identified foreign substance(s).

To our knowledge, this protocol as published by USDA has not been followed. Had it been followed, the industry would have been well informed as to findings during the continued testing of the technology, and would have had the opportunity to comment on any apparent discrepancies or concerns with the application of the technology, to assist in gaining information relevant to the potential residual effect of non-injurious compounds, and to modify practices as needed to avoid false positive tests. This would have made the industry more knowledgeable and comfortable with the use of the GC/MS, and more secure in its ability to provide accurate results.

In the recently published USDA comments, it was stated several times that USDA has been testing the GC/MS tool for three years, and that USDA believes that the three years of testing should have provided ample opportunity for the industry to adjust practices to avoid foreign substance violations. While the USDA may have been collecting samples over a three year time, no results were provided to the industry until early 2008. Those results were only for 14 events in the year 2007. We believe far more transparency on this issue is needed and far more information must be provided to the industry on its use before USDA progresses to the imposition of penalties based on results.

We have several specific questions or comments in reference to some of USDA's responses, and on a few additional issues.

1) USDA's response to point number three of the HIO comments concerning the validation of the technology states:

> "Beginning in the 2004 show season, USDA tested the GC/MS tool in the horse show environment. USDA worked with HIOs to establish a baseline for positive results of foreign substances. We shared these baselines with the HIOs during this time. After 3 years of continuous sampling conducted at randomly selected horse shows, the controlled amount has been detected by running .0001% benzocaine standard for every 5th sample."

We would like to request a copy of this baseline for positive results that was shared with the HIOs in 2004 so that we can share it with our members. Also, please explain further the comment "After 3 years of continuous sampling conducted at randomly selected horse shows, the controlled amount has been detected by running .0001% benzocaine standard for every 5th sample." Which controlled amount are you referring to? Was the test standardized for benzocaine only during these trials?

2) USDA's response to point number four of the HIO comments requesting that the industry be notified of test results on the horses, states:

> "Because USDA has been testing the effectiveness of the GC/MS rather than using it for enforcement over the past three years, trial testing has been random, both by show and by horse. We fully disclosed to the HIOs that we would select horses randomly and would therefore not share reports on specific horses….. While we did not inform specific owners or

> trainers of results on their horses, they have had access, through their HIO representatives, to information on the test's general results. They are in the best position to know whether they themselves have been using these substances and whether they should adjust their practices."

This response is in direct opposition to the testing procedures USDA published in its 2006 press release. Furthermore, during the three years of testing, no test results were provided until the 2007 results were released in early 2008. Those testing results only reported that there were positive and negative results with no correlation to any known status or specific horse. If an owner or trainer had their horse swabbed in Feb 2007, for example, even if they had inquired, they would not have had results available until a year or so later. It would be very difficult to then correlate results back to specific compounds that may have been used, and more importantly, when they had been applied. Furthermore, if upon inquiry they had learned that 14 of 20 samples were positive (which was the case in the results listed for the February 2007 Kentucky After Christmas Sale), how would they know if a non-injurious substance they may have applied a few days before the show had been detected? Without knowing this information, how would they know if they needed to make adjustments? Therefore, we do not agree with USDA's conclusion that all involved have had ample opportunity to adjust practices to avoid foreign substance violations.

3) USDA's response to point number five of the HIO comments which questioned how long before a show trainers need to be sure to not use any cosmetic or other non-injurious salves in order to avoid having the sniffer register positive greatly concerns us. The response states in part:

> "We have not studied this specific issue and cannot recommend that trainers ensure any particular time between using any cosmetic or other non-injurious salves in order to not have a positive response from the GC/MS test. But the key point is that USDA will focus on, and use its enforcement discretion on, foreign substances that are considered irritants, numbing, and masking agents. We do point out, however, that the HPA Regulations state: All substances are prohibited on the extremities above the hoof of any Tennessee Walking Horse or racking horse while being shown, exhibited, or offered for sale at any horse show, horse exhibition, or horse sale or auction, except lubricants such as glycerine, petrolatum, and mineral oil, or mixtures thereof: "

It is inconceivable to us that the USDA would not evaluate the issue of residual cosmetic or other non-injurious salves potentially causing a positive response to the GC/MS test yet would consider pursuing federal cases against those who have potentially innocently used such substances.

We understand that the HPA regulations state that all substances are prohibited on extremities above the hoof of any Tennessee Walking Horse or Racking Horse while

being shown, exhibited, or offered for sale. However, the Horse Protection Act Section 2 (3) states in part:

> "the term 'sore' when used to describe a horse means that..
> … (d) any other substance or device has been used by a person on any limb of a horse or…*and, as a result of such application, infliction, injection, use, or practice, such horse suffers, or can reasonably be expected to suffer, physical pain or distress, inflammation, or lameness when walking, trotting, or otherwise moving,…*" (emphasis added)
>
> Although the HPA regulations Section 11.2 (c) prohibits all substances above the hoof of any Tennessee Walking Horse while being shown, exhibited, or offered for sale, paragraph (a) of the same regulation states in part:
>
> (a) General prohibitions:
>
> "…no chain, boot, roller, collar, action device, nor any other device, method, practice, or *substance* shall be used with respect to any horse at any horse show, horse exhibition, or horse sale or auction *if such use causes or can reasonably be expected to cause such horse to be sore."* (emphasis added).

It is clear from the HPA itself, as well as the opening paragraph in the regulations, that the intent of the Act and the regulations is to prohibit substances that would be applied for the purpose of causing pain or discomfort to the horse. The intent is not to prohibit non-injurious salves or lotions that may be used for other reasons.

Moreover, the HPA regulations do not prohibit the use of cosmetic or other non-injurious salves in the days *prior* to the horses being presented for show or sale. Without understanding anything about the detection of residual substances that may have been applied days or longer before, the evaluation of the GC/MS technology in the horse show environment can not be considered complete. This evaluation needs to be conducted and the results shared with the industry so that owners, trainers, and handlers have every opportunity to be in compliance.

4) USDA's response to point number seven in the HIO comments is incomplete. The request was for protocols for the use of the GC/MS test at horse shows, including appropriate collection and handling of samples.

USDA shared a protocol provided by the National Veterinary Service Laboratories in 2006 outlining how to obtain, submit, and ship samples. While we appreciate that information, we are also requesting that a horse show protocol regarding collection of samples be developed and shared with the industry for comment prior to implementation. This will ensure that the implementation protocol is sound, and well understood by the industry.

For example, what does "random selection" mean in practice? What method will be used to randomly select horses and who will make that determination? How will USDA avoid bias in the selection process? What information will be collected at the time a horse is

swabbed? Once the sample gets to the lab, what constitutes a "positive" or "negative" sample? What are the detection threshold levels? How fast will results be reported back to the owners and trainers?

Currently, the same swab is used to sample both front legs. Section 6(5) of the Horse Protection Act states:

> "In any civil or criminal action to enforce this Act or any regulation under this Act a horse shall be presumed to be a horse which is sore if it manifests abnormal sensitivity or inflammation in *both* of its forelimbs or *both* of its hind limbs."

How will the sampling be conducted? We believe an individual swab should be taken on each forelimb. If a substance is found on one limb only, it should not be considered in violation of the HPA, especially if that substance happened to be a contaminant.

5) USDA's response to point number eight in the HIO comments regarding the list of prohibited chemicals states:

> "We recognize that there are legitimate uses for sulfur and that not every use is intended for improper purposes. However, we are considering elemental sulfur to be a foreign substance that would warrant a penalty because experience and investigation tell us that it is sometimes used to prevent scarring on the pasterns of a horse's front limbs. Therefore, we must consider elemental sulfur to be a masking agent."

As USDA acknowledges, there are legitimate uses for sulfur and sulfur is a component of several frequently used, non-injurious compounds. As such, we request USDA obtain a more thorough understanding of the compounds that contain sulfur and the use of those compounds before making the decision to add sulfur to the list of foreign substances that would warrant a penalty. In the 2007 GC/MS results recently published, 42% of the substances detected included elemental sulfur. In 32% of the cases, elemental sulfur alone was detected. USDA refers to sulfur as a "masking agent." What is the definition of a "masking agent?" If a "masking agent" but no other chemicals are found, what is the "masking agent" assumed to be masking, and what is that assumption based on? Without understanding the parameters for residual substance detection, and recognizing that there are legitimate uses for sulfur containing compounds, it is clear that the proposal to issue penalties for the presence of sulfur needs to be revisited.

6) USDA's response to point number nine in the HIO comments which recommended that the proposed technology, associated validation data, and protocols for use be reviewed by an independent scientifically-based third party to help ensure the science of sound and proposed application of the technology is appropriate states:

> "USDA's National Veterinary Services Laboratories (NVSL) will conduct the testing. NVSL is recognized by the World Organization for Animal Health as an international reference laboratory for animal diseases and has proven capability to handle testing far more sophisticated than that

> involved here. This laboratory handles all confirmatory testing for all infectious animal diseases.
>
> We believe that NVSL's international recognition reflects strong third-party endorsement of its credibility. Nevertheless, we are currently in the process of receiving the ISO 17025 accreditation specifically for the GC/MS test."

We would like to point out that the reason for raising this point was not because of a concern of NVSL's laboratory capabilities. The reason for making this recommendation was based on a concern of a lack of what we consider appropriate validation data, the lack of data regarding potential violations caused by residual substances, and other such concerns previously discussed. In light of these concerns, we still feel it is best to have a scientifically-based third-party review of the technology and its associated data, and the proposals for how the technology is to be used to ensure that it is scientifically sound and will be used fairly and appropriately.

(7) We strongly recommend that prior to using the GC/MS to take official action, an additional research and education effort be undertaken. To initiate this action, the requested information as outlined above regarding sampling and testing protocols should be developed and distributed for comment. This should be followed by a "free" clinic, in which trainers or owners could bring horses and have them swabbed. Dual swabs should be collected. One would go to NVSL, and one would go to an independent laboratory and the results compared for quality control and verification purposes. At this "clinic", the proposed protocols for sampling would be discussed, and any other concerns or questions would be addressed. Once sampling results are received, test results would be discussed, and further information would be gathered on any horses that had positive results regarding types and timeframes of substances used. Results of this initial effort could then be analyzed to either define further information needed, or to support moving ahead with use of the GC/MS as part of the enforcement process.

This process will serve to foster and maintain excellent communications and trust, and to validate the use of the GC/MS technology in the horse show environment. Up until this time, there has been no data that we are aware of that correlates either positive or negative test results to any known information regarding types and timeframes of substances used in the horse show industry. It will also allow time for HIO and show management to review their documentation and requirements and amend as necessary.

In summary, we recognize that these comments may seem to indicate that we are not in favor of the use of the GC/MS technology. That is not the case at all. We fully support and recognize the value of the use of new technology to identify those who are truly violating the Horse Protection Act. However, as we've stated before, it is absolutely critical that the industry be provided with the information and guidelines it needs to be able to be in full compliance. It is critical, especially if new technology will be used to bring federal cases, that the parameters under which it will be used and potential unintentional impacts on results are documented and well understood by the industry. Questions such as the length of time that residual non-injurious components will be

detected must be answered. It is imperative that during this process, owners, trainers and handlers of horses that are swabbed receive results in a timely manner, so they will have proper information on which they can act to either modify the time frames for use of certain compounds, or explore the use of alternate, legal compounds. We feel that once the areas of concern are addressed, and findings have been provided in a timely manner so the industry has an understanding of and trust in the use of the GC/MS, it could be a useful tool to aid in the enforcement of the Horse Protection Act.

We look forward to your reply.

Sincerely,

Frank Neal, Chairman
National Horse Show Commission, Inc.