Horse Protection Commission

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Dr. Rachel Cezar Horse Protection Coordinator USDA/APHIS, Animal Care 4700 River Road, Suite 6D03 Riverdale, MD 20737

RE: Bill Hawks, Ag Works Solutions, Comments on Protocol for Foreign Substance Penalty

Dear Dr. Cezar:

We are in receipt of a copy of comments by Bill Hawks, Ag Works Solutions, which are in response to the USDA proposed Protocol for Foreign Substance Penalty. We would like to address each aspect of Mr. Hawks' letter with which we disagree.

Mr. Hawks' first point states:

1) First of all, there is an Operating Plan currently in place for the 2007 - 2009 show seasons. The majority of HIOs are currently following this operating plan, which has been agreed to by USDA. There was a significant investment in both time and energy by the HIOs and USDA, including some very difficult negotiations, to reach agreement on this Operating Plan. This Operating Plan references and includes foreign substance violations of the Horse Protection Act. Since this Operating Plan is currently in effect, the penalties as outlined in it should be the ones that remain in place throughout the 2007 - 2009 show seasons. Any additional changes such as the addition of federal penalties should be discussed with the industry for the next iteration of the Operating Plan. To do otherwise calls into question the sincerity, integrity, and necessity of the Operating Plan.

First, the Operating Plan states numerous times that it does not supersede the HPA or regulations. As such, if the Plan is preventing the intended effect of the HPA in any way, then it is automatically in conflict with the HPA, in which case improved measures of enforcement should always prevail.

An excerpt from Section VIII E. 1. of the Plan states:

"The DQP or VMO also shall look for evidence of prohibited substances, and prohibited or non-compliant paraphernalia or devices."

A second excerpt from Section VIII E. 3. states:

"This examination shall include, but not be limited to, digital palpation procedure, examination for evidence of scar rule violations, evidence of prohibited substances, and prohibited or non-compliant paraphernalia or devices."

A third excerpt from Section VIII C. states:

"The DQP or VMO may carry out additional inspection procedures or conduct additional tests, such as but not limited to examining rear limbs, using hoof testers, fluoroscopy or x-ray, as deemed necessary, to determine whether or not a horse is in compliance with the HPA."

Taken together, and consistent with the intentions of the HPA, the foregoing references make clear that the plan actually provides for use of devices such as gas chromatography-mass spectrometry (GC-MS) at any point that they assist in determining compliance. In addition, another excerpt from Section III of the Plan states:

"If changes are requested under this review process and APHIS determines that changes are necessary in order for the Plan to achieve its intended purpose, they will be made at the appropriate time."

Therefore, Plan itself provides for adjustments that APHIS deems appropriate, which would clearly include adjustments to penalties where a reasoned case can be made for those adjustments. In this instance, changes to the Plan are unnecessary, as this is an investigation and action by the Department, and should ultimately be the enforcement responsibility of the Department, including the implementation of a federal case and assessing of penalties to the trainer, owner and exhibitor. Since, the swab is done pre-show and the horse is allowed to show, unless other non compliant issues are detected. Any positive lab results would come after the horse exhibited in the class, sale or exhibition. Therefore, this would constitute a post show violation and should be litigated as such.

Mr. Hawks' second point states:

2) Unfortunately, this appears to be another eleventh hour change by the Department, just as the show season is about to start. Last year, the Department did the same thing, by making a policy decision to pull the probation period out of the Operating Plan a week or two before the show season started. The industry needs to be notified well in advance of policy decisions that could significantly impact them, so that productive discussion can occur and a level of trust in the system can be developed. Also, in order for a national program to be effectively implemented, it is critical that policy changes be introduced in such a way that the industry has adequate time to respond. Ideally, any proposed changes should initially be introduced in the fall, well prior to the start of the show season.

First of all, it was primarily the WHTA/NHSC who dragged their feet until the "eleventh hour" by significantly exceeding the deadline for submission of the draft Plan to the Department. Historically, such draft Plans do undergo changes during review by the Department before the finalized Plan is returned to the industry. As such, this situation was typical except for the delays caused by the industry. Perhaps Mr. Hawks had lost familiarity with this process.

Secondly, the Walking Horse Trainers Association has repeatedly and publicly insisted that only a very small percentage of horses are sore. If one accepts that notion, then the "significant impact" is only significant to that very small percentage that is in violation. Since it is given that they are in violation, sound logic dictates that policy should not revolve around them. It would also then seem in the best interest of the vast majority of competitors to improve and increase the enforcement capability as soon as the technology is deemed acceptable for use. This logic only breaks down if, in fact, there is a much larger percentage of the industry that is not in compliance, and that have only escaped detection due to prior, less capable methods that allowed them such escape. Again, policy should not be determined by those who are in violation.

Mr. Hawks' third point states:

The WHTA supports the appropriate use of new technology in the inspection process. Before new technology is introduced however, the technology needs to be validated for use in the horse show environment and the data needs to be shared with the industry. This will ensure transparency and trust in the new technology and will allow the industry an opportunity to ask any questions, and raise any concerns. Before the new gas chromatography/mass spectrometry (GC/MS) test is used to bring federal cases, we respectfully request the following information:

Data showing how the technology was validated for use in the show environment,
and/or for use on the legs of horses. How many positive tests were correlated back to
known substance use on horses? How many negative tests were correlated back to
horses known to be free of all substances?

What is the sensitivity and specificity of the test in a horse show environment? (i.e. expected level of false positive and false negative results?)

As you know, GC-MS is very robust, but not new technology. It is well-established, proven and accepted technology that is employed in a wide variety of applications in science and industry. The technology does not require validation in this specific application, as its function is simply to determine the presence and amounts of substances, just as it is used in a host of other applications. Put another way, from the point of view of the instrument, this application is not unique.

There is a massive amount of data, both in literature and in actual use, demonstrating the veracity of this technology. As such, it is our position that no purpose is served by subjecting this method to question by this industry except in a court of law as part of a federal case.

Mr. Hawks' fifth point:

- 5) The WHTA will work to ensure that trainers do all they can to be in compliance with the HPA. To help ensure that the "sniffer" technology works as it should without causing false positive results and in the interest of transparency, we request some guidelines on its use that can be provided to the trainers. For example;
 - a. How long before a show do trainers need to be sure to not use any cosmetic or other non-injurious salves in order to avoid having the "sniffer" register a positive response? Although the HPA states that no foreign substance other than show provided lubricants are allowed on a horse's leg while at a show, there are many non-injurious substances that may routinely be used on a horse for a variety of reasons prior to the show, such as soap residue from bathing, or hoof blacking dye. What is the latest these types of non-injurious substances can be used without causing positive tests? There is an article titled "Determination of clenbuterol in horse hair by gas chromatography—Tandem mass spectrometry" by Popot et al in. In that study which was done to investigate drug detection in samples of horse hair from the coat (on the neck), mane, and tail, three clenbuterol studies were conducted on a total of four horses. The study indicates that a retrospective analysis-measurement of clenbuterol in the tail was possible for up to 13 months after the last administration of drug. This may or may not correlate to use of the "sniffer" at horse shows, but raises some concerns regarding residual substances that may be detected.

What if trainers/handlers have hand cream on or OTC antibiotic cream on their own hands? How much can get transferred by handling horses feet before causing a positive test? Do trainers and others need to use gloves?

I received the following paragraphs upon review of one of HPC's technical advisors, who is an analytical chemist:

Mr. Hawks' cites the Popot, et al, paper as potentially raising "concerns regarding residual substances that may be detected." However, the paper cited, as well as several other similar papers, describes a method for determination of compounds that are contained within the hair shaft itself, requiring digestion or milling of the hair followed by solvent extraction of the compounds of interest, then followed by GC-MS analysis. These methods usually involve, as an initial step, cleansing the hair of any external contaminants (i.e. washing with 1:1 water + methanol) that could potentially interfere with analysis of the compounds contained within the hair itself. Since the method cited requires breakdown of the hair for the determination of compounds within it, those methods have no bearing whatsoever on the sampling and

samples at horse shows, taken for GC-MS analysis, which analysis is for the determination of substances which are <u>external</u> to the hair itself. In fact, the hair itself is in no way involved in the sample or analysis for determination of the presence of foreign substances per the HPA, regulations, or Plan.

It is abundantly clear that there is no relationship between the sampling/swabbing at horse shows for substances topically applied and external to the hair and the fact that hair may contain within itself residues of drug administered up to 13 months prior to analysis of the hair. Residues within the hair would never be a factor in the APHIS protocol, as there is no digestion and extraction of compounds from the hair itself. Considering the importance of this issue, it is somewhat disturbing that Mr. Hawks may not have realized that distinction when citing the subject paper as having potential bearing on the "sniffer" as applied to this industry. However, even more disturbing is the prospect that he understood that distinction, as evidenced by the phrase "This may or may not correlate to use of the "sniffer" at horse shows,", and then chose to cite the paper anyway.

Further, we disagree with Mr. Hawks that it is necessary for the industry to be involved in determining what might be acceptable levels for foreign substances. For the record, soap is in fact used to sore horses, by applying the soap to the pastern and wrapping in plastic. In regard to hoof black, this should be applied to the hoof only. There is no reason for hoof black to be applied to the pasterns. The industry's focus and understanding of what is acceptable regarding the presence of foreign substances should remain what is described and demanded by the Act, regulations and Plan, which is none. Swab samples collected by the Department, without prior announcement, from horses at shows inspected by sound HIOs clearly demonstrate that false positives are not an issue in this protocol. Mr. Hawks is certainly within reason when he states that trainers would need to know about how long before a show they should refrain from the use of such substances. We believe the Department's best response is for the trainers to ask those who have been swabbed only to go on showing without issue.

In summary, Mr. Hawks' contention that the Plan precludes the swabbing of horses, analysis of those swabs by proven technology such as GC-MS, and adjustments to penalties based on results from such samples and tests is utterly without merit. Neither an Operating Plan nor any of these issues should ever be used as impediments against or to delay enforcement of the Act. While the industry has never failed to state that they support enforcement of the HPA, their track record disputing that is abundantly clear. Their tactic of debating and stalling is only once again exemplified by this letter from their most recent hired gun, Ag Works Solutions. While the industry wants to engage in hair-splitting over what is an acceptable limit versus what is not, their focus should instead be on what the HPA demands, which is no sore horses, and in this specific instance, no foreign substance.

It is not the Department who is being disingenuous by carrying out their charge of enforcing the HPA and improving their ability to do so by employing new technology, such as the "sniffer". It is the industry who continues to demonstrate bad faith by fighting at every turn any improvements in enforcement while simultaneously insisting that only a very small percentage of horses are in violation. Their focus is on regulating soring and defining limits that they can push instead of focusing on the spirit and intent of the HPA, which was to create a deterrent that would serve to abolish this cruel practice. As such, we sincerely hope that the Department will not be drawn into a debate on limits regarding this protocol, but will move forward aggressively to implement it, issuing warnings for a first offense followed by federal cases for subsequent violations. Again, the data collected from sound HIOs clearly demonstrates that people who abide by the law will have no difficulty with this protocol.

Respectfully,

Donna Benefield Administrative Director

Cc: Dr. Chester Gipson
Mike Tuck, USDA
Robin Lohnes, USDA/F

Robin Lohnes, USDA/HIO Facilitator HPC Commission

Advisory Board

Encl: Bill Hawks' Response to Foreign Substance Protocol