USDA's Responses to HIO comments on Foreign Substance Penalty

1) 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.

USDA supports the Operating Plan and continues to believe it is an important component of joint Federal-Industry efforts to prevent soring of horses. Given the unique shared enforcement provisions of the Horse Protection Act (HPA), it is necessary and we too believe that all signatories must enter into the Plan with sincerity. Also, all signatories must carry out their part of the Plan with integrity. However, we do not believe that the protocol is in conflict with the Operating Plan or its penalty provisions. The Operating Plan clearly states that its purpose is not to supersede the HPA or regulations, or to in any way limit USDA's authority. Very specifically, 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."

Additionally, 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."

Given the above references, USDA believes that the protocol is contemplated by the Plan, and the protocol's establishment in no way reflects upon the Plan's necessity, nor USDA's sincerity in entering into it, nor its integrity in carrying it out.

Additionally, we note that the protocol will involve only Federal penalties, and not those deemed the responsibility of the Horse Industry Organizations (HIO). We do not believe that the Plan precludes USDA from assessing Federal penalties or that it places any restrictions on the Federal Government's authority to determine penalties; that authority remains with USDA and the Plan does not and cannot negate that authority. However, in a sincere attempt to enforce the HPA in the cooperative spirit envisioned by the Plan, we have designed the protocol to give a fair opportunity for all those regulated to comply with it. The graduated penalty structure provides ample opportunity to adjust practices as necessary before a violator faces significant penalties.

Finally, in this instance, we believe that changes to the Plan are unnecessary, as this protocol involves only inspections and actions by USDA. 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 handled as such.

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.

USDA has been testing the Gas Chromatography/Mass Spectrometry (GC/MS) tool for three years and has discussed its use in determining foreign substance violations and penalties many times at HIO face-to-face meetings and conference calls. In fact, it was initial feedback from those HIO meetings that led to the draft penalty protocol that contemplated having the HIOs apply penalties for a second offense. (We subsequently decided not to adopt that provision given the chain of custody concerns raised by HIOs and others). Additionally, we have provided another full opportunity for comment over the past several weeks. The graduated penalty structure takes into consideration the concerns raised. We believe that the three years of testing, many meetings over that time, and this most recent opportunity for comment have provided for a productive discussion. Further, we believe that all involved have had ample opportunity—and will have even additional opportunities-to adjust practices to avoid foreign substance violations.

3) 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?)

The GC/MS test can separate and identify chemicals individually, and therefore it is widely regarded as the "gold standard" for forensic substance identification. It is used to perform a specific test. A specific test positively identifies the actual presence of a particular substance in a given sample. As a result, it is highly unlikely to ever produce false positives. If anything, its specificity focus could lead to more false negatives.

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.

Results from 2007 Gas Chromatography/Mass Spectrometry tests conducted on a random selection of horses at shows were shared with the 14 certified HIOs. There was nothing to indicate that the horse show environment was so unique as to invalidate this otherwise widely-accepted technology. In fact, it appears that regular horse handling practices before shows are more likely to reduce rather than cause random environmental substances to adhere to a horse's pastern.

While we have confidence in the GC/MS technology, we will carefully monitor the results this year as we implement the protocol. We welcome feedback from all interested parties as we monitor our results.

4) Although the new GC/MS test has been used on a trial basis at horse shows, the industry has only been provided summary data findings. Owners have not been notified of test results on their horses, and therefore have not known when there was a need to take any corrective action. Before the new GC/MS test is used to bring federal cases, we respectfully request that for the 2008 -2009 show seasons, the GC/MS trials continue and that owners of all horses tested be notified of results.

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. The three year trial was intended to verify if the GC/MS test would detect chemicals known to be irritating, numbing, and masking agents known to be in violation of the Horse Protection Act. We believe that test was successful, and we have shared the types of foreign substances most often detected, especially those that would be considered irritating, numbing, and masking agents that clearly would

constitute violations of the HPA. 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.

We believe that the protocol, with its two-warning (with specificity about the detected foreign substance) provision, provides fair notice and specificity for owners and trainers to adjust their practices before they face significant penalties.

5) 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?

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: Provided,

> That:
> (1) The horse show, horse exhibition, or horse sale or auction management agrees to furnish all such lubricants and to maintain control over them when used at the horse show, horse exhibition, or horse sale or auction.
> (2) Any such lubricants shall be applied only after the horse has been inspected by management or by a DQP and shall only be applied under the supervision of the horse show, horse exhibition, or horse sale, or auction management.
> (3) Horse show, horse exhibition, or horse sale or auction management makes such lubricants available to Department personnel for inspection and sampling as they deem necessary.

6) 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?

USDA will focus on foreign substances that are considered irritants, numbing, and masking agents. It may be prudent for trainers who have applied such agents to their own hands to wear gloves when having to handle the horse's front pasterns at any given time prior to exhibition.

7) Protocols for use of the GC/MS test at horse shows need to be developed and distributed prior to its use, including appropriate collection and handling of samples.

Please see the attached protocol developed by the National Veterinary Service Laboratories that details how to obtain, submit, and ship samples. Before we implement the protocol, we will distribute this to all USDA VMOs who will obtain the samples.

8) Through the process of obtaining data, evaluating and making conclusions based on scientific evidence, and proper experimental procedure, we have the opportunity to make learned judgments. With this in mind, could you provide the HIO's with information relative to "control" information and subsequent Gas Chromatography/Mass Spectrometry list of foreign substances? Although no list is ever "complete" it would be beneficial for horse owners/trainers to know specifically which ones are foreign.

We have screened the following chemicals over the past 3 years:

Camphor
Menthol
Benzocaine
Sulfur
Isopropyl Palmitate
Fuel Oil Components
O-Aminoazutulene
Lidocaine
Isopropyl Myristate
Octyl Methoxycinnamate
Silicone-based Components (i.e. Dimethicone)

Glycerin, Mineral Oil, and Petrolatum are the only allowed chemicals not to be considered a foreign substance and are not documented as a positive result.

Please note that these are not the only chemicals that are screened for and some chemicals that are considered positive may not be noted as a foreign substance. Therefore, USDA will focus its prosecutorial discretion on foreign substances that are considered irritants, numbing, and masking agents.

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. Of course, we will continue to analyze the list of substances believed to be used as irritating, numbing, or masking agents and make adjustments if warranted. We welcome any input as we continue that analysis.

9) *The proposed technology, associated validation data, and protocols for use should also be reviewed by an independent, scientifically based third-party to help ensure that the science is sound and proposed application of the technology is appropriate. An example of such a committee would be the United States Animal Health Association (USAHA) Committee on Animal Welfare. The membership of the USAHA is crosscutting and includes state and federal regulatory animal health officials as well as industry. The stated mission of the USAHA Committee on Animal Welfare is: "explores animal welfare concerns and seeks to present data in an honest, unbiased, science-based manner for USAHA membership to evaluate. In this capacity, the committee serves as a forum for promoting dialogue between the various animal welfare groups and industry and for promoting the development of broad-based animal welfare solutions". This type of scientifically based external review will help protect the integrity of the program, and is general practice for other USDA animal health related programs.*

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.

Additional questions from SSHBEA

10) If this is not possible, at least give the HIO's the opportunity to come up with a penalty structure that could possibly be incorporated in the current 2007-2009 Operating Plan.

We believe that there are two major reasons why the penalty structure must remain Federal-only at this time. First, only Federal VMOs will take the samples. This raises significant chain of custody issues since this testing procedure does not include the HIOs. Second, the Operating Plan focuses more on industry penalties applied after findings by DQPs. We are contemplating bringing

administrative enforcement actions ("Federal cases") after a certain number of violations. Accordingly, we believe that the entire penalty structure must remain Federal as long as only Federal VMOs take the samples and Federal administrative enforcement actions may result from any findings.

11) The Spotted Saddle Horse Breeders and Exhibitors Association feel as though the USDA allowed the SSHBEA to participate in all the other penalty and/or structure plans, but we did not have the opportunity to participate or voice our concerns in the "partnership" plan with the USDA that involved the Gas Chromatography/Mass Spectrometry (GC/MS) test.

USDA has communicated with the HIOs over the past three years as we contemplated using this technology. This recent opportunity for full comment was another attempt to encourage participation. We value all the input and recognize the concerns. We have tried to address many of the concerns in the spirit of partnership. For example, we provided for two warnings and the offer of a stipulation before we would bring an administrative enforcement action ("Federal case.") We have attempted to be consistent as possible with both a cooperative spirit and our duty to enforce the HPA.

Additional questions from SHOW

12) Relating directly to the question, it appears to me all HIO's that signed the Operating Plan signed a good faith plan for 2007-2009. Included in this plan there exists a violation and penalty protocol for foreign substance. It would appear to me, as a novice to this group that Gas Chromatography/Mass Spectrometry would follow on the heels of the existing document violation relative to foreign substances and the penalty phase.

It is important to note that the HIOs should still follow the Plan and its penalty structure for foreign substance violations that DQPs identify. The GC/MS protocol applies only to samples taken by USDA VMOs. We believe that the objectivity of the GC/MS test provides stronger evidence of the use of irritants, numbing, and masking agents than might be available through regular inspection procedures. Given our duty to enforce the HPA and work to eliminate soring, we believe we are obligated to apply a progressive penalty protocol to deter repeat offenses. We believe this will move us closer toward our shared goal of eliminating soring.

Additionally, we note that the protocol will involve only Federal penalties, and not those deemed the responsibility of the HIOs. We do not believe that the Plan precludes USDA from assessing Federal penalties or that it places any restrictions on the Federal Government's authority to determine penalties; that authority remains with USDA and the Plan does not and cannot negate that authority. However, in a sincere attempt to enforce the HPA in the cooperative spirit envisioned by the Plan, we have designed the protocol to give a fair opportunity for all those regulated to comply with it. The graduated penalty

structure provides ample opportunity to adjust practices as necessary before a violator faces significant penalties.

13) As I listened to all parties I was surprised that you (USDA) introduced the Gas Chromatography/Mass Spectrometry as a 1-2-3. Previously, the HIO's were involved and allowed to negotiate literally every phase of the Operating Plan. However, in this instance no involvement or negotiation by HIO's was allowed relative to the penalty phase.

We believe that three years of discussion followed by this specific time for comment provided significant opportunities for involvement. In fact, we have amended the draft protocol after listening to concerns. We will continue to carefully review the protocol's implementation and welcome continued input and dialogue.