Horse Protection Commission

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June 6, 2008

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

Re: HIO response to USDA GC-MS Protocol

Dear Dr. Cezar:

We have received a copy of a letter from an HIO to the USDA dated May 29, 2008, further addressing their concerns regarding the implementation of GC-MS for foreign substance detection. The letter is shown in its entirety below, with our point-by-point responses embedded within it, in bold and preceded by the word "**Response**:"

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.
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- 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.

Response:

Results were published on samples collected prior to the 2007 season, were posted on the APHIS website, and were downloadable. In fact, after seeing those results, some within the industry, not realizing that those results included a large number from an NWHA show, concluded that GC-MS was proving that the industry was largely in compliance. Perhaps over-confidence was responsible for the lack of inquiries regarding that data.

The Act and Regulations make no reference to "non-injurious compounds", and do not define them. The only allowed substances are mineral oil, petrolatum, glycerin, and mixtures thereof. Further, the Department is not in the business of recommending other substances or practices to be sure trainers are in compliance. That responsibility lies entirely with trainers, owners, and exhibitors.

The definition of a false positive is a positive result for a compound that is not actually present in the sample. GC-MS does not produce false positives, meaning that if a material is not present in a sample, GC-MS will not show a positive result for it. The capabilities of the GC-MS instrument technology is well established in both science and industry, and is well beyond being subject to review by the Walking Horse industry, who have no standing to perform such a review. The industry's lack of comfort stems not from any truly questionable nature of the instrumentation or method, but instead from the fact that it is, indeed, beyond question and well removed from their long-held and highly prized claim of "subjectivity".

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.

Response:

The industry has been fully aware of the use of this instrumentation on a trial basis. However, they have been fully aware of the law as well, which states that foreign substances are illegal. The law has not changed here, but only the method of detecting those in or out of compliance with it. Since the industry has been well aware of the law as well as that APHIS was gathering data on this method, they have had more than ample opportunity to assure themselves of being in compliance with the law.

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?

Response:

The use of check samples or standards is a standard practice in analytical labs. The benzocaine analyses were clearly used as check samples, containing a known/measured amount of benzocaine in order to ensure that the instrument was stable and not drifting

during the course of the analysis. Although internal standards are commonly used with GC-MS, which automatically compensate for instrument drift, check samples are still used to verify instrument stability. The check sample does not re-standardize the instrument, but provides a measurement to ensure that it is remaining in standard. For a routine analysis situation, it would appear that running a check every five samples is more than sufficiently rigorous, given the method.

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.

Response:

APHIS did publish results of testing well prior to 2007 on their website. Secondly, the results need not be correlated to a "known status or specific horse" in order to be valid. The samples were measured against standards of known quantity. The primary purpose for making results available to the industry is to demonstrate the improved capability of the method for detecting foreign substances. Trainers' and owners' responsibilities have not changed, as the law has not changed. Directly in line with the original intents and

purposes of the Act, the purpose of disallowing foreign substances is to bring about an end to their use involving soring at home and in the training barn; not merely at a show.

Substances referenced by the industry as non-injurious substances are simply illegal under the Act. It is well known that violators have always claimed what they are using is "non-injurious". For good reason, the Department has stated what is allowed rather than attempting to define on a substance by substance basis what is not allowed. The regulations were intentionally written broadly enough to capture not only irritants, but also compounds which could be used to temporarily mask or hide the irritants and/or their effects. Further, it is our view that proper training methods should not result in the routine need for foreign substances. The lubricants described in the Act and Regulations should be adequate when used with legal action devices to avoid injury to tissues. If the industry questions whether the currently defined legal action devices cause harm, then perhaps the use of action devices should be revisited.

Further, as previously mentioned, a large number of swab samples were taken at an NWHA show on horses otherwise inspected and determined to be not sore. The 100% negative results on horses at that show demonstrated that horses shown under normal show conditions will not show positive for foreign substances under this protocol when such substances are, in fact, not present.

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.

Response:

It is not the Department's responsibility to make recommendations to trainers and exhibitors regarding anything they use on a horse other than the lubricants allowed by law. It is the Department's responsibility to enforce the law, which clearly states that anything other than the allowed lubricants is illegal. While data suggests that there may be a significant number of horses that have been in violation of the law, there also exists a large population of data on horses that have been shown in compliance with the law, as demonstrated by this technology. As such, it is quite clear that presenting a compliant horse is not difficult. Quite simply, it is the responsibility of each horse trainer/owner/exhibitor to ensure that their horse is in compliance with the HPA.

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.

Response:

The reasons are evident as to why the Act and Regulations are not restricted to only those compounds that cause a horse to be sore. The presence of masking and numbing agents in swab samples shows the wisdom of that breadth of coverage. Those compounds are used by violators in an attempt to skirt the law and enforcement of it by temporarily hiding the effects of soring agents, methods, practices and devices.

While the HPA does not prohibit the use of any substance on a horse in the days prior to being presented for show or sale, its purpose is most certainly to provide a disincentive and deterrent against the use of chemicals which would cause a horse to be sore at any time, including in the days *prior to* a show. As such, the presence at presentation of anything that could be used to hide, mask, or promote healing of prior injury from soring is illegal, including what might be considered by some to be "non-injurious compounds".

Furthermore, we fail to understand the necessity of "cosmetic or other non-injurious salves" on horses' legs. This concern by the industry raises the question as to what is being done to these horses that such salves and "cosmetics" are necessary in the first place. If the HPA is about ending the practice of soring, then what is the logic behind making provisions for steps taken to help heal or hide the injuries resulting from it? It is in neither the USDA's nor the horse's best interest to make such a provision, which is essentially what is being requested.

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?

Response:

The notion that horses will be randomly selected does in no way prohibit the Department from the non-random selection of horses to be tested, particularly if the Department believes a particular horse deems additional inspection to determine whether it is in compliance with the Act. However, if any change is made in this policy, we would support all horses being swabbed at shows attended by the Department.

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.

Response:

There is currently no distinction between a single foot and both feet regarding foreign substance. If the horse is positive on one or both feet, it is in violation, and will receive the appropriate penalty. Appearance of foreign substance on one foot could indicate an attempt to "level" a horse, or otherwise numb or mask an issue with one foot due to soring.

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.

Response:

Some Walking Horse trainers may believe that elemental sulfur prevents scar tissue. Outside of Walking Horse lore, even a cursory study of the subject reveals that elemental sulfur cannot be used by the body, whether equine or human, in any way in the regeneration of tissue. The literature does note, however, that elemental sulfur is commonly employed as a keratolytic (peeling) agent, used to remove the outer layer of skin, which may have an effect on the formation or removal of scurf that develops as a result of soring. In that case, it would be functioning to mask or hide evidence of soring. However, whether or not it is used in that regard, it should remain illegal as a foreign substance. There are literally hundreds, if not thousands, of sulfur compounds. Opening the door to one will invariably invite inquiries for others. The Department would do well to avoid altogether the approval of substances on a compound by compound basis. In addition, as evidenced by the large number of horses that have been shown without indicating positive for such substances, these compounds are necessary for the proper training and showing of horses. Further yet, many substances such as sulfur have both legitimate and illegitimate uses. The only logical answer is to disallow them altogether, as allowing them in any form or fashion will shortly lead to their abuse.

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.

Response:

The use of GC-MS in a wide variety of applications in science and industry has been more than fully validated, and needs no further validation specific to enforcement purposes under the HPA. The instrument simply detects for the presence of foreign substances and measures the levels of them on the sample swab. Since it is clear that those who engage in the practice of soring attempt to remove any evidence of their practice, it is reasonable that only residual evidence will remain. It is precisely that residual evidence that this technology will serve to identify. It bears repeating that the HPA concerns itself with assigning guilt based on evidence of soring that presumably occurred *prior to* the horse being presented at a show or sale. Its purpose is to remove the incentive to engage in the practice altogether and at any time during the training of horses by not allowing those who so engage to benefit by it.

(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.

Response:

One clinic had already been conducted early on regarding this technology. However, unless one is more than a cursory understanding of such instrumentation and the associated protocols, it is unlikely that a clinic will significantly further improve "familiarity". Regardless, such a clinic should not come at the expense and in advance of enforcement of the law. The comment period has ended, and the validation issue has been addressed. Again, the law has not changed, but only the method of detecting violators. The change here is analogous to using a radar gun to detect speeders rather than a stop watch. The speed limit remains the same.

While they say that they are not questioning the NVSL capabilities, swabs sent to two labs is a clear indication of just that. It was pointed out by APHIS that NVSL functions as a

reference laboratory, meaning that they set the standard against which other labs measure themselves. There is little doubt that the NVSL participates in laboratory round-robin testing to verify their capabilities right along with other participating labs. If such round-robin data is available, it would be our recommendation that NVSL simply share that data as evidence of their testing capabilities. Beyond that, if the industry wishes to use 3rd-party testing to challenge NVSL results, then that challenge should come as part of the defense against a federal case.

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.

Response:

Again, it is not necessary for the horse industry to validate the use of GC-MS. GC-MS is a test method that has more than ample validation, and is used throughout science and industry. Using an aforementioned analogy, insisting that the Walking Horse industry validate GC-MS for the detection and measurement of foreign substances is analogous to speeders validating the radar gun technology before it was put into use, which is simply nonsensical.

The law is plain and clear, and has been on the books for decades regarding the use and presence of foreign substances. The adjustment period should have taken place within two weeks after the law was passed in 1970. Proclaiming the necessity of a period for "adjustment" or to "amend" practices in order to ensure compliance is tantamount to admission of being in violation of the Act.

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.

Response:

To summarize:

1) **The industry had ample knowledge of the ongoing use of GC-MS on a pre-enforcement basis. No further "adjustment period" is warranted.**
2) **The law regarding the presence of foreign substance is clear, is not new, and has not changed.**
3) **This technology removes the argument of "subjectivity" regarding foreign substance.**
4) **The veracity of this technology is well documented and does not require validation or a comfort level by the Walking Horse industry, who has no standing to question its merits.**
5) **Neither elemental sulfur, nor any other compound, especially those which would fall under irritants, numbing agents and masking agents, including those which could be used to mask, hide or heal past or present injury directly related to soring, should be excluded.**
6) **No change should be made to the sample protocol which calls for a single swab for both front feet.**
7) **The argument for "cosmetic or non-injurious salves" begs the question as to why they are necessary in the first place. No provision should be made for them, as they provide cover for abuse.**
8) **It has been well documented that horses can be successfully shown under this protocol. Clearly, more of them will be shown free of foreign substance with this protocol in place.**
9) **It is not the Department's responsibility to tell trainers how to be in compliance or make recommendations in that regard. It is simply their responsibility to enforce the law.**
10) **It is solely the responsibility of trainers, owners and exhibitors to be in compliance with the law.**

In conclusion, this industry has complained incessantly for years about "subjectivity" in the inspection process, that claim clearly serving as a thinly veiled excuse to question rigorous enforcement of the Act. Now that non-subjective methods are being introduced, they don't know what to do with them.

Violators of the HPA should not benefit from soring, whether past or present. The very purpose of the HPA was to remove the incentive to engage in the practice of soring at home

and in the training barn *prior to* a show or sale by disallowing horses which have been subjected to that practice from participating in those events and penalizing those who have so engaged. If practices have been used that cause injury to the horse which requires ongoing treatment with "non-injurious" salves, then this protocol should be used to catch and penalize such violators rather than making a provision for them under the guise of some dubious argument for their "legitimate" use. Such an argument has the word "bogus" written all over it.

With GC-MS, the industry no longer has the crutch of "subjectivity" where foreign substances are concerned. However, true to form, the industry questions the validity of this technology in yet another effort to stall, dilute, and negate enforcement efforts. It is our sincere hope that the Department will stand steadfast behind this technology and the protocols in place. If any change is made, it should be only regarding sampling of ALL horses at a show rather than sampling randomly. This is one of the few tests during inspection that no amount of "schooling" a horse can beat. It is hoped that this technology will usher in a new period in which additional technologies, such as thermography and algometry will shortly even further lay to rest claims of subjectivity by the industry. Perhaps finally, these technologies will come to bear on those who have unfairly benefited by skirting the law for so long.

They asked for it. They got it. Now they don't know what to do with it.

Respectfully yours,

Donna Benefield
Administrative Director
Horse Protection Commission