

January 2014

FOREIGN SUBSTANCE ISSUES - Details

First, and foremost, the Tennessee Walking Horse industry embraces science-based inspections in enforcement initiatives. In June 2012, the Walking Horse Trainers Association in concert with the Tennessee Walking Show Horses Organizations (the precursor to PSHA), launched an industry program implementing and funding the swabbing of the feet of horses in order to detect substances that harm the house or mask substances that have harmed the horse. Repeated requests were made in the implementation of this program for partnership from the USDA, AVMA, and AAEP to help identify substances to be tested for as well as baseline and tolerance levels. They all refused to work with the industry to establish a scientifically sound swabbing program.

SUBSTANCES CURRENTLY TESTED FOR BY THE USDA

The USDA has repeatedly stated that it would be testing for substances it considered to be "irritating, numbing, and masking agents that clearly would constitute violations of HPA." However, at no time have they provided any information as to how they scientifically determine a substance is "irritating, numbing, or masking" and specifically at what levels any substance is deemed to be "irritating, numbing or masking." A copy of "Foreign Substances in 2008 Defined" is attached along with "Foreign Substances Found" from the USDA's presentation at the Sound Horse Conference. In June 2008 the USDA announced its "Protocol for Foreign Substance Penalty," also attached. However, to date, there has been no information provided to the industry as to what substances are actually tested for, much less how it was determined that the substances tested for actually violate the HPA by altering the horse's gait or masking the inspection process.

In all the established equine drug testing programs, forbidden substances are considered as those with a potential to affect performance, provide an unfair advantage, or potentially dangerous to the horse. The rules are not intended to discourage the proper veterinary care of horses if such treatment would not threaten any of the important objectives. It has long been recognized that horses in training, like all athletes, will at times require the administration of certain therapeutic medications to preserve their health and welfare. A performance-altering substance is a substance not identified as a therapeutic medication or any substance with no accepted therapeutic use in horses in training, showing or racing, excluding substances that are

endogenous, dietary, or environmental. Endogenous, dietary, or environmental substances are substances produced within or by the horse itself (endogenous) or that may unavoidably become part of the food supply (dietary) and or environment of horses (environmental).

Foreign Substances listed in the USDA's Report are found in personal care products such as cosmetics, shampoos, conditioners, lotions, ointments and general over the counter first aid products. Compounds found in products used on a routine basis for **all breeds** of horses such as fly spray, grooming products and therapeutic medications, together with substances that are endogenous, dietary, or environmental are also cited as HPA "violations."

By way of example, set forth below are several substances identified by the USDA as "irritating, numbing or masking" and therefore HPA "violations":

Isopropyl palmitate and myristate: [cosmetic lotion]: Found in shampoos, Palmolive soap being one of them. It is considered an "indispensable ingredient" in high quality shampoos and conditioners. Http://www.naturalwellbeing.com/learning-center/Isopropyl_Palmitate

Elemental sulfur: Elemental sulfur is present in every cell and is structurally and functionally important in more that 150 compounds in the body including tissues, enzymes, harmones, antibodies and antioxidants. **In animals**, the **highest concentration of sulfur is found** in the joints, **hair, skin** and nails. It is known as "nature's beauty mineral."

o-Aminoazutulene = [dye i.e., hoof black polish]: A grooming aid used in showing - cosmetic - a substance that makes a horses hooves shiny and "pretty." Legally used by most all breeds, and **approved for use by the USEF**.



Octyl Methoxycinnamate: This is a product found in most all equine fly sprays, typically in most barns, and has a residual effect for at least 14 days. Allegations are that it blocks thermography but without any scientific basis as to how much of this compound it takes to block a thermograph exam its definition as a prohibited substance is highly suspect.

The NHBPA, USEF, FEI all have substances considered to be "forbidden." These are drugs that can affect performance giving an unfair advantage and pose a danger to a horse. There is no therapeutic use for these substances in the equine world. Such substances would certainly be "allyl isothiocyanate" [mustard oil] and/or "crotoris oleum - phorbol" [croton oil] which are products/compounds alleged to rampantly being used to sore Tennessee Walking Horses. Yet, to the best of our knowledge, none of these compounds has been found on the USDA's Foreign Substance violation reports.

Given these examples, it is impossible to say that each "positive" swab result reported by the USDA was the result of the application of a substance to the horse's limb which was intended to alter the horse's gait or mask inspection. The failure of the USDA to identify the substances to

be tested for as causing irritation and/or masking results is a false positive result and improper because no scientific link to a soring violation of the HPA has been provided.

LEVELS OF SUBSTANCES FOUND IN USDA SWAB RESULTS

In addition to failing to identify actual substances which could have irritating and/or masking affects, the USDA has also failed to establish tolerance levels/baselines above which a detected substance can said to have an irritant and/or masking affect. Instead, the USDA's current swabbing program utilizes a "zero tolerance" level and reports as "positive" any swab result which has substances present at any level. This "zero tolerance" testing being conducted by the USDA as below 1 part per million or 1 part per billion simply establishes there is a **presence** of a substance - testing down to these very low levels, not how much is there [concentration] and definitely not whether there is a potential to affect performance, provide an unfair advantage, or is potentially dangerous to the horse is scientifically inappropriate.

Zero Tolerance testing is defined as utilization of the most sensitive and rigorous testing procedures possible for the substance in question, encompassing the full scope and sensitivity of modern analytical technology. As such, the analytical limit defined by **zero tolerance** policy "testing" is simply the "**limit of detection**" [LOD] of the most sensitive testing technique available. **Zero tolerance policy testing**, therefore, continually increases in sensitivity as analytical methods improve and as technology has increased the capability to detect to a "picogram" (pg) which is **one trillionth** of a gram and beyond. In perspective, one part per billion to everyday life, represents one second in your life if you are 32 years of age. One part per trillion is one second in your life if you are 32,000 years of age.

In the spring of 2008, in a response to the "baseline" for testing, the USDA stated that "...the controlled amount has been detected by running .0001% benzocaine standard for every 5th sample."

This is one part per billion, which is equivalent to ONE DROP of water diluted into a 10,000 gallon swimming pool,

or a pinch of salt to a 10 ton bag of potato chips.

The USDA initiated a Foreign Substance Program under the HPA in 2004 using the Znose which has been used at airports for years to detect explosive compounds. This was abandoned in 2005. In 2006 the USDA announced swabbing of the pasterns [ankles] of the TWH would

undergo testing at the USDA's National Veterinary Service Lab using GC/MS which can "...detect minute amounts of substances." Numerous letters seeking information and expressing concerns of environmental contaminant, cosmetic, therapeutic product, as well as thresholds, cut-offs, and detection times were made to the USDA, however very little information was provided

by the USDA. On June 29, 2012, at the Tennessee Walking Horse of Today Equine Conference [TTEC], the USDA stated that it has been testing at **LESS than 1 ppm (one part per million)**. No explanation as to how much "less than" is, but this is equivalent to "less than" one drop of water diluted into the fuel tank of a compact car **or about 32 seconds out of a year**.

In 1991 the McKinsey Report, addressing drug testing in the racing industry, stated that:

"The industry should develop test specifications, especially bottom cut-off sensitivity levels, to reduce positive that are not meaningful."

Continuing this line of thought, the American Association of Equine Practitioners (AAEP), in its 2000 Policy of *Therapeutic*¹ *Medication*² *in Racehorses*, stipulates that:

"Detection of pharmacologically-insignificant levels of therapeutic medications <u>should</u> not constitute a violation of medication rules."

Dr. Steven Barker is chemist for the Louisiana State Racing Commission. In his study on *Drug Contaminates Problems For Zero Tolerance* presented during the NHBPA committee meeting in February 2007, Dr. Baker reported that "racehorses can come into contact with drug residue just about anywhere." "Small quantities of 6 drugs were found in samples taken from stalls, test barns and pools of water at Louisiana racetracks." Even dust samples were tested and "trace amounts of substances were found." Some drugs were detected "from just wiping the interior of stalls". Baker warned that "with highly sensitive testing methods and zero-tolerance policies, a trainer could be charged with a positive of having one molecule of a substance in a sample." He went on to explain other potential sources of trace amounts of drugs "are feed, pasture, grasses, improper handling of samples and mistakes by veterinarians." Dr. Barker also claimed about 80% of drug positives fall under the category of having no impact on a horse outside of 24 hours. Dr. Barker went on to say "These comments I've heard that any level (of a substance) could potentially have an impact on performance is crap!"

EQUINE DRUG TESTING

The Racehorse drug testing began in the early 1900s. It is the longest established, broadest in scope, and possibly the most sensitive drug testing program in existence. Like the government's SAMHSA program for workplace testing, it is performed using blood and urine with published thresholds. Leading drug testing in equine research is *The National Horsemen's Benevolent and Protective Association* (NHBPA). Dr. Thomas Tobin, a world leading expert in this field, is a

¹ Therapeutic: Definition: serving to cure or heal or to preserve health

² Therapeutic Medication: Definition: Administered by or under the supervision of a veterinarian that supports the health, welfare, and fitness of horses during training, showing and racing or facilitates their safe and humane handling during routine procedures

co-author of the NHBPA. He is a veterinarian, pharmacologist and toxicologist, and professor at the Gluck Equine Research Center, Department of Veterinary Science and the Graduate Center for Toxicology, University of Kentucky. He is well published and has testified before Congress. His research support is approximately \$15 million through 2012. **Thresholds** and **withdrawal times** are scientifically researched and published by the NHBPA.

The United States Equine Federation [USEF] is reportedly the largest sport horse testing program in the world and has operated its own laboratory since 1995. It is the national governing body for equestrian sports and is a member of the U.S. Olympic Committee. It is responsible for enforcing the rules of over 27 breeds and disciplines. It utilizes over 100 veterinarians and scientist. The USEF contracts with state and national association for testing, including the Federation Equine International [FEI] which is the international governing body of equestrian sports headquartered in Switzerland and the American Quarter Horse Association [AQHA] in implementing their drug and medication programs. Again, **thresholds** and **withdrawal times** are scientifically established and published.

The USDA has never established or published any thresholds and withdrawal times.

QUANTITATIVE vs. QUALITATIVE:

At least three major approaches to the problem of medication control have evolved, none of which has been found to be entirely satisfactory: 1) **quantitative** "thresholds"; 2) "detection times"; and, 3) withdrawal time guidelines." Of these, quantitative "thresholds" are, in scientific and regulatory terms, found to be the most satisfactory solution.

QUANTITATIVE - is a test that **both unequivocally identified and establishes the concentration** of the prohibited substance in the test sample. This is the test that is **universally** used by science based testing programs such as the Federal Workplace Drug Testing Program ["SAMHSA"], United States Equine Federation and the Federation Equine International.

QUALITATIVE - is a test that **simply identified the <u>presence</u>** of a prohibited **substance** in the test sample - **not the concentration**. This is the testing being done by the USDA in its Foreign Substance Program under the HPA. There is no documented proof as to what level a substance has any effect, i.e., one drop of water in a 10,000 gallon swimming pool, if the substance is a residual from a therapeutic medication, an environmental contaminant, a natural occurring substance, or dietary.

USDA'S TESTING & THRESHOLDS: THE 52 out of 52 REPORT:

The Humane Society of the United States [HSUS] has attacked the compliance statistics of the industry, as well as those of the USDA, based on the percentage of foreign substances found via swabbing the hair on the pasterns [ankles] of our horses alleging that "...these substances are numbing agents and drugs that mask evidence of abuse...." They have stated numerous times,

including in a Petition for Rule Making, that "...of the 52 horses tested at the Tennessee Walking Horse National Celebration every single horse tested positive for illegal agents."

To be very clear - to-date the USDA has never provided any scientific proof as to what is "irritating, numbing or masking," at what levels any substance would be "irritating, numbing or masking," and definitely not whether there is a potential to affect performance, provide an unfair advantage, or potentially dangerous to the horse - which is the standard for every other breed in the equine world! A copy of the "52 out of 52 Report" is attached.

To-date, no federal cases have ever been filed and only "letters of warnings" have been sent to individuals. Unbelievably those notices have been posted on the USDA's website without any ability of the trainer, owner or exhibitor to challenge the "determination" of an illegal "foreign substance."

Can one claim that the 96.7% to 98.5% of the TWHs that go thru the most stringent inspection in the world, i.e., x-ray, thermography, palpation, locomotive testing [walking and turning in small circles] to be non-compliant for a 1 part per million or billion molecule of any of the above substances found on hair on their ankles? Non-compliant and an HPA violation for a minute molecule equivalent to a pinch of salt to a 10 ton bag of potato chips or less than a drop of water in a 10,000 gallon swimming pool?

In perspective: USDA inspectors themselves test "compliant" with less than 2,000 ppb [ng/ml = 1 ppb] of Morphine in their urine. The Tennessee Walking Horse with .0001% [1 ppb] on the hair on its ankle is "non-compliant" and subject to Federal Prosecution. At race tracks in Ohio and Louisiana limits for Morphine are established at 75 ppb and 50 ppb respectively, compared to 2,000 ppb for government employees. These testing limits for all equine, except the TWH, are very conservative when compared with the limits in place in human forensic testing. The limit of one part per billion being used by the USDA in its Foreign Substance Program, applicable only to the TWH industry, is totally unrealistic and without any scientific bases.

CONCLUSION

Technology is capable of helping eliminate soring in the TWH industry. The Industry requests that it be treated like all other breeds, including the 27 breeds and disciplines tested by the USEF



and others. No other breed is subject to zero tolerance testing for any substance without providing any scientific proof as to what is "*irritating, numbing or masking*," at what levels any substance would be "*irritating, numbing or masking*," and definitely not whether there is a potential to affect **performance, provide an unfair advantage, or is potentially dangerous to the horse.**

The Tennessee Walking Horse industry embraces science-based inspections in enforcement initiatives. The Industry stands ready to work with the USDA and any other organization in the development of scientific based Foreign Substance testing with scientifically defined and based thresholds as well as totally prohibited substances.



HORSE PROTECTION PROGRAM FOREIGN SUBSTANCES IN 2008 DEFINED

| FOREIGN SUBSTANCES FOUND | DEFINITIONS |
|---|--|
| Aromatic hydrocarbons consistent with the composition of a fuel oil | Used as commodity chemicals in the petrochemical industry. These compounds are one of the most widespread organic pollutants, remaining on beaches and marine environments for a long time after an oil spill. A counterirritant.* |
| Benzocaine | Is a local anesthetic. A numbing agent. |
| Elemental Sulfur | Uses are primarily in production of agrichemicals and fertilizers, detergents, dyestuffs, and widely used in black gunpowder and matches. Also used in acne and skin treatments, commonly used as a keratolytic (skin peeling) agent. A counterirritant and masking agent. |
| Octyl Methoxycinnamate | Is considered an ultraviolet screen. Have been used to possibly camouflage thermography image. Causes transdermal absorption of other chemicals. A masking agent. |
| Isopropyl Palmitate | Is the ester of isopropyl alcohol and palmitic acid. It is most commonly found in cosmetic products as a synthetic moisturizer and emollient. Examples are liquid detergents like Palmolive. A counterirritant. |
| o-Aminoazotoluene | Used in the coloring of oils, fats, and waxes and in the manufacture of pigments. It is also a chemical intermediate for the production of dyes. Causes skin sensitization. It is reasonably expected to be a human carcinogen and is a prover carcinogen in animal studies. A counterirritant and masking agent. |
| Camphor | Is readily absorbed through the skin and produces a feeling of cooling similar to that of menthol and acts as slight local anesthetic and antimicrobial substance. A counterirritant and numbing agent. |
| Oxybenzone | Is considered an ultraviolet screen. Have been used to possibly camouflage thermography image. Causes transdermal absorption of other chemicals. A masking agent. |
| Methyl Salicylate | Is prepared by the esterification of salicylic acid with methanol. It is used in perfumery, but also has therapeutic use as a counterirritant. Synonyms include: wintergreen oil, betula oil, sweet birch oil and teaberry oil. Under Caution:"Direct contact may cause irritation of the skin and mucous membranes." A counterirritant. |
| Isopropyl Myristate | Is used in cosmetic and topical medicinal preparations where good absorption through the skin is desired. A jellied isopropyl myristate was marketed as Estergel. A counterirritant. |
| Lidocaine | Is a local anesthetic. A numbing agent. |
| Dimethly Sulfoxide (DMSO) | Is rapidly absorbed through skin and mucous membranes; enhances dermal absorption of many chemicals. Repeated topical application may result in mild, erythematous, scaling dermatitis" A counterirritant. |
| Menthol | Has local anesthetic and counterirritant qualities, and it is widely used to relieve minor throat irritation. A counterirritant and numbing agent. |

 $^{^*}$ Counterirritant = 1 : an agent applied locally to produce superficial inflammation with the object of reducing inflammation in deeper adjacent structures 2 : an irritation or discomfort that diverts attention from another http://www.merriam-webster.com/dictionary/counterirritant

USDA's POWER POINT PRESENTATIONS Foreign Substances Found:

2007:

Future Plans for USDA

- Continue working with HIOs
- Outreach:
 - Public Awareness
 - Working with associations
 - American Associations Equine Practitioners
 - · American Farrier Associations
 - Breed Associations: WHTA WHOA TWHREA
 - Animal Interest Groups: AHPA, HSUS, HWF
- Use of new technology
 - Foreign Substance Testing
 - Thermography Examinations

Foreign Substance Penalty Protocol

- Provided draft to HIO at last face-to-face meeting
- Allowed comments to protocol and will provide comments back to HIOs
- Plan to implement a penalty protocol by May 1, 2008

Foreign Substances Found

- Camphor, Methyl Salicylate = Irritant
- Isopropyl palmitate and myristate = Cosmetic lotion
- Elemental Sulfur = Known to possibly prevent scar tissue
- Benzocaine, Lidocaine = Anesthetic
- o-Aminoazutulene = Dye (i.e. hoof black polish)
- Octyl Methoxycinnamate = Sunscreen known to possibly block thermography
- Menthol
- Fuel Components

2008

Foreign Substances Found

- 13 substances found
- Counterirritants = Fuel oil, Isopropyl Palmitate (Palmolive), Methyl Salicylate, Isopropyl Myrisate, Dimethyl Sulfoxide (DMSO)
- Numbing Agents = Lidocaine, Benzocaine
- Masking Agents = Octyl Methoxycinnamate (sunscreen), Oxybenzone
- Counterirritant and masking agent = Elemental sulfur, o-Aminoazotoluene,
- Counterirritant and numbing agent = Camphor, Menthol



USDA Horse Protection Program

Protocol for Foreign Substance Penalty

Beginning June 1, 2008, USDA will take the following actions in response to a foreign substance violation detected by a USDA inspector through use of the Gas Chromatography/Mass Spectrometry (GC/MS) Test:

1st offense: Issue official USDA warning (Form 7060) for violation of Federal Regulations to all parties involved.

2nd offense: Issue official USDA warning (Form 7060) for violation of Federal Regulations to all parties involved.

3rd offense: Offer a stipulation to the alleged violator in accordance with the Horse Protection Act Regulations (9 C.F.R. § 12.10). If the alleged violator does not accept the stipulation, USDA will initiate an administrative enforcement action (commonly known as a %Eederal case+).

4th offense: USDA will initiate an administrative enforcement action (commonly known as a %Eederal case+).

Additional Information

- Samples for the GC/MS test will be randomly collected by USDA officials only.
- Tests will be conducted by USDA APHIS National Veterinary Services Laboratories in Ames, IA.
- Turnaround time of results may vary. To ensure that alleged violators have adequate notice to adjust their practices after learning of a violation, USDA will not consider a second offense to have occurred for any foreign substance detected by a GC/MS test from the time of the first offense to the time the alleged violator has received notice of the first offense.
- USDA will notify the alleged violator of the specific foreign substance or substances detected concurrently with the notification of the penalty.
- If multiple horses of an alleged violator are tested at one show competition, only one penalty will be applied.

USDA will focus its prosecutorial discretion on foreign substances that are considered irritants, numbing, and masking agents.

Definition of Foreign Substance

As stated in the Horse Protection Regulations, Sec. 11.2 (c):

- (c) Substances. 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.



HORSE PROTECTION PROGRAM

2011 FOREIGN SUBSTANCE RESULTS



TWH Celebration Aug 31-Sep 3, 2011 (Shelbyville, TN) Tested 52 : Positive 52

Isopropyl myristate, Lidocaine, Isopropyl Palmitate, o-aminoazotoluene, Sulfur, and Vitiman E acetate

o-aminoazotoluene and Octyl methoxycinnamate

Sulfur and one plasticizer

Benzocaine, Lidocaine, o-aminoazotoluene, and Octyl methoxycinnamate

Methyl salicylate, Butylated Hydroxytoluene, Benzocaine, Lidocaine, Glycerin,

Methylparaben, and Various Hydrocarbons

Benzocaine, Lidocaine, o-aminoazotoluene, Octyl methoxycinnamate, Sulfur, 1,4-bis[(1-methylethyl)amino] 9,10-Anthracenedione, and Cholesterol

Benzocaine, Isopropyl myristate, Lidocaine, Sulfur, and Cholesterol

Benzocaine, Lidocaine, Octyl methoxycinnamate, and Multiple Glycols

Decamethylcyclopentasiloxane, Benzocaine, Lidocaine, Octyl methoxycinnamate, Cholesterol, and Multiple Glycols

Methyl Salicylate, Lidocaine, and Multiple Hydrocarbons

Isopropyl myristate and Lidocaine, Sulfur, and Multiple Hydrocarbons

Isopropyl myristate, Isopropyl Palmitate, o-aminoazotoluene, and Vitamin E acetate

Lidocaine, o-aminoazotoluene , Sulfur, 1,4-bis[(1-methylethyl)amino] 9,10-

Anthracenedione, and Cholesterol

Decamethylcyclopentasiloxane, o-aminoazotoluene, Octyl methoxycinnamate, Sulfur, 1,4-bis[(1-methylethyl)amino] 9,10-Anthracenedione, Cholesterol, and one acid ester

Benzocaine, Lidocaine, o-aminoazotoluene Multiple Glycols, and one acid ester

Benzocaine, Lidocaine, o-aminoazotoluene, and Sulfur

O-aminoazotoluene and 1,4-bis[(1-methylethyl)amino] 9,10-Anthracenedione

Lidocaine and Sulfur

Lidocaine, Octyl methoxycinnamate, and one phthalate ester

Lidocaine, Sulfur, and Cholesterol

Benzocaine, Lidocaine, o-aminoazotoluene, and Multiple Glycols

Benzocaine, Isopropyl palmitate, o-aminoazotoluene, and Multiple Hydrocarbons

Lidocaine, Isopropyl Palmitate, Various Hydrocarbons, Cholesterol, and one plasticizer

Lidocaine, Multiple Hydrocarbons and Cholesterol

Isopropyl Palmitate and Various Hydrocarbons

Benzocaine, Lidocaine, and Sulfur

Lidocaine, Isopropyl Palmitate, Sulfur and Cholesterol

Octamethylcyclotetrasiloxane, Decamethylcyclopentasiloxane, Benzocaine, Isopropyl Palmitate, Octyl methoxycinnamate Sulfur, Cholesterol, and multiple acid esters

Benzocaine, Lidocaine, Sulfur, and Cholesterol

Benzocaine, o-aminoazotoluene, Octyl methoxycinnamate, and Multiple Glycols

Decame thyl cyclopentasiloxane, Benzocaine, Octyl methoxycinnamate, Sulfur, and Multiple Glycols

Benzocaine, Isopropyl myristate, Isopropyl Palmitate, o-aminoazotoluene, Vitamin E acetate, Cholesterol

Decamethylcyclopentasiloxane, Octyl methoxycinnamate, and one acid ester

Octamethylcyclotetrasiloxane, Decamethylcyclopentasiloxane, Salicylic acid, Multiple Hydrocarbons, and Cholesterol