UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

FRONT RANGE EQUINE RESCUE, *et al.*, Plaintiffs, v. TOM VILSACK, Secretary of the U.S. Department of Agriculture, *et al.*, Federal Defendants.	Civil No. 1:13-cv-00639 **DECLARATION OF DANIEL L. ENGELJOHN, Ph.D.**

I, Daniel L. Engeljohn, declare and state the following:

1. I make the following representations based upon my personal knowledge and upon facts made known to me in my capacity as an official of the Food Safety and Inspection Service ("FSIS") of the United States Department of Agriculture ("USDA").
2. I am the Assistant Administrator for the Office of Field Operations ("OFO"), FSIS, USDA. I have been employed by USDA for more than 34 years. Throughout my service with FSIS, I have been involved with ensuring food safety, protecting the public health, and managing public health risks associated with meat, poultry, and egg products. My educational background includes a Bachelor of Science degree in animal science from the University of Illinois, a Master of Science degree in meat science and muscle biology from the University of Illinois, and a Ph.D. in human experimental nutrition from Howard University.
3. In my career at USDA, I gained strong expertise in developing effective food safety and quality control procedures for the production of food products. For the first six years of my career with USDA, I was the primary author of the meat purchase specifications developed by the Agricultural Marketing Service, USDA, that were used by USDA's Food and Nutrition Service and the Department of Defense in the procurement of ground beef for distribution to both the National School Lunch Program and the feeding of soldiers. I joined FSIS in 1985, and during the next 27 years I was the primary author of the risk management strategies associated with the safety of meat, poultry, and egg products, with particular expertise in developing policies to ensure that *Escherichia coli* O157:H7 (*E. coli* O157:H7), a highly virulent food borne pathogen primarily associated with beef, is effectively addressed by the meat industry. I also served until 2012 as the

agency's scientific liaison with the research and academic community, industry, public citizens, and foreign, State, and local governments on risk management strategies for effectively controlling food safety hazards of public health concern. In 2002, I became the Deputy Assistant Administrator for the agency's Office of Policy, Program and Employee Development. My primary responsibility is to write all regulations governing the strategic risk management activities of the agency, as well as the instructions for implementing those regulations that were directed at the agency's field inspectors.

4. I have held my current position as Assistant Administrator of OFO since May, 2012. My primary responsibility is to provide executive management of the agency's inspection programs authorized by the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. § 601 *et seq*., the Poultry Products Inspection Act, 21 U.S.C. § 451 *et seq*., and the Egg Products Inspection Act, 21 U.S.C. § 1031 *et seq*. I serve as the senior executive responsible for the roughly 8,500 federal inspectors who conduct daily inspection of meat and poultry food products or processing of egg products. I also oversee ten District Offices that manage the aforementioned inspection programs in all fifty States.

5. FMIA requires government inspectors to conduct an ante-mortem inspection of cattle, sheep, swine, goats, horses, mules and other equines, 21 U.S.C. § 603; a post-mortem inspection of the carcasses and parts of the same, 21 U.S.C. § 604; and an inspection of meat food products during processing operations, 21 U.S.C. § 605, in establishments that sell or distribute in commerce meat that is intended for human consumption.[1]

[1] Section 19 of the FMIA also requires that meat and meat products derived from horses and other equines be "plainly and conspicuously marked or labeled or otherwise identified . . .to show the kinds of animals from which they were derived." 21 U.S.C. § 619. Pursuant to this mandate, the meat inspection regulations contain extensive marking and labeling requirements for carcasses, meat, and meat food products derived from equine. For example, "the immediate

Establishments that intend to slaughter cattle, sheep, swine, goats, horses, mules and other equines to produce meat that is intended for human consumption and sale or distribution in commerce are required to apply to FSIS for a grant of federal inspection in accordance with the requirements in 9 C.F.R. Part 304. The District Offices process the grants of inspection for the establishments that are located and operate within their District boundaries.

6. FSIS's regulations specify the regulatory requirements that establishments must meet in order to receive a grant of federal inspection. For example, before receiving a grant of inspection, an establishment must have in place written sanitation standard operating procedures and a Hazard Analysis and Critical Control Points ("HACCP") plan that specifies how it will control food safety hazards that are likely to occur in its production process. *See* 9 C.F.R. § 304.3. The regulations further provide that the Administrator is authorized to "refuse to grant inspection if he determines that the applicant and/or the establishment does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§ 416.1 through 416.6 of this chapter, or that the applicant has not received approval of labeling and containers to be used at the establishment, as required by the regulations in parts 316 and 317." 9 C.F.R. § 304.2(b).

7. As of the date of this declaration, FSIS has received applications for federal inspection from six establishments that wish to engage in the commercial slaughter of horses, mules,

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containers of any equine products shall be labeled to show the kinds of animals from which derived when the products are sold, transported, offered for sale or transportation or received for transportation in commerce." 9 C.F.R. § 317.9. Additionally, the official inspection legend required to be affixed to inspected and passed carcasses and meat food products from equine is shaped differently from the inspection legend required for carcasses and meat food products of other livestock and it must contain the words "horse-meat"/"horse-meat product" or "equine-meat"/"equine-meat product." 9 C.F.R. §§ 312.3 and 327.26.

and other equines. FSIS received an updated equine slaughter application from Valley Meat Company, LLC, in Roswell, New Mexico, on March 15, 2013, and the agency's District Office, in Dallas, Texas, issued the grant of federal inspection on June 28, 2013. FSIS received an application from Responsible Transportation, LLC, in Sigourney, Iowa, on December 13, 2012, and the agency's District Office in Des Moines, Iowa, issued the grant of federal inspection on July 2, 2013. A third establishment, Rains Natural Meats in Gallatin, Missouri, submitted an application to the District Office in Springdale, Arkansas, on January 15, 2013, and its grant of inspection is in the final stages of review pending its compliance with the requirement in 9 C.F.R. § 304.2(c)(1) that it submit to FSIS a State certification that there is reasonable assurance that the establishment's activities will be conducted in a manner that will not violate the applicable water quality standards.[2] The other three establishments (Unified Equine LLC in Rockville, Missouri; Oklahoma Meat Company in Washington, Oklahoma; and Trail South LLC in Auburntown, Tennessee) have not actively pursued completion of the grant process after the first submission of their applications to FSIS.[3] One of the facilities, Trail South LLC, was known at the time of its first interaction with FSIS not to have begun construction of the building to house its slaughter activities. Thus, at this time, Rains Natural Meats is the only additional establishment that can feasibly complete a successful grant application for equine slaughter and be ready to slaughter equine in the near future,

[2] This State certification is the certification required by section 401 of the Clean Water Act (33 U.S.C. § 1341(a)).

[3] Unified Equine LLC submitted its application on April 25, 2012; Oklahoma Meat Company submitted its application on May 18, 2012; and Trail South LLC submitted its application on June 1, 2012.

following approval of the grant and the taking of steps to hire and train employees and to arrange for slaughter stock and buyers of the product.

8. Generally, the slaughter process for equines, including the handling of inedible material, is no different than that for any other livestock (e.g., cattle, swine, sheep, or goats). The inedible material is separately marked and controlled to ensure that it does not get used for human consumption. In addition, Federal, State, and local public health requirements ensure the proper handling and disposal of inedible material. Other Federal, State and local government entities enforce these requirements.

9. There are some requirements that apply to equine slaughter establishments that differ from other livestock slaughter operations. Specifically, FSIS's regulations require that the slaughter or other preparation of products of horses, mules or other equines be conducted in establishments separate from any establishment in which cattle, sheep, swine, or goats are slaughtered or their products are prepared. 9 C.F.R. § 305.2 (b). This requirement is not due to special zoonotic diseases or pathogens inherent in equines. Rather, this restriction is in place to better ensure that there is no species substitution of equine meat product with other livestock meat product. FSIS has the expertise to conduct species identification in food samples and does so for domestic and imported food products under its jurisdiction.

10. There are also minor differences in the drug residue testing procedures for equines. The U.S. National Residue Program ("NRP") is an interagency program that is conducted in collaboration with the Environmental Protection Agency ("EPA") and the Food and Drug Administration ("FDA"). The program is designed to identify, rank and test for chemical contaminants, including approved and unapproved veterinary drugs, pesticides and

environmental compounds, in food, including meat, poultry and egg products that are regulated by FSIS. The FDA, pursuant to the Federal Food, Drug and Cosmetic Act, approves animal drugs and establishes tolerances for those drugs, and sets action levels for food additives in all food, including meat, poultry and egg products. The EPA, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act, establishes tolerance levels for registered pesticides, and sets action levels for environmental contaminants. FSIS conducts sampling and testing of products within its jurisdiction, specifically, meat, poultry and egg products, in order to ensure that the products do not exceed the tolerances established by FDA and EPA. FSIS has conducted sampling and testing of meat and poultry products, including equines, since 1967.

11. Sampled horse carcasses are required to be held by the horse slaughter establishment until it receives test results from FSIS. When FSIS detects a chemical compound level in excess of an established tolerance or action level set by FDA or EPA, or for which no such tolerance or action level has been established by those agencies, the carcass is considered adulterated, as defined by 21 U.S.C. § 601(m)(2), and is condemned. FSIS also shares the test result with FDA, which has on-farm jurisdiction, and with EPA. FDA and cooperating State agencies investigate producers linked to residue levels in excess of established tolerances and, where warranted, can bring legal action against the producer.

12. Representatives from FSIS, FDA, EPA, USDA's Agricultural Research Service, USDA's Agricultural Marketing Service, and the Centers for Disease Control and Prevention meet annually in a collaborative effort to develop scheduled sampling programs for chemical compounds in meat, poultry and egg products. The sampling programs are based on prior findings of chemical compounds in these products, FDA veterinary drug inventories

completed during on-farm visits, information from investigations, and pesticides and environmental contaminants of current importance to EPA.

13. The NRP has evolved over time to respond to emerging and re-emerging chemical residue concerns and improved testing methodologies. For example, in 2012, FSIS announced that its laboratories would begin using new multi-residue methods on all tissue samples of livestock from selected carcasses intended for human consumption as part of a major restructuring of the NRP. *See* 77 Fed. Reg. 39,895 (July 6, 2012). This restructuring of the NRP began in earnest in approximately 2009 when FSIS initiated work on validating new rapid screening methods for detecting drug residues in-plant in livestock kidney and muscle tissue. Since equines were not allowed to be slaughtered from approximately 2006 until 2011 due to congressional de-funding of the inspection program, equines were not part of the restructured NRP. However, once equine slaughter inspection was again funded and at least one request for a grant of inspection was presented to FSIS in late 2011, FSIS began the process of validating the new multi-residue methods for equine tissue. On June 28, 2013, FSIS also announced through the June 28, 2013 FSIS Constituent Update (Volume 15, Number 25) that several of the Chemistry Laboratory Guidebook methods had been modified to include equine tissue along with other livestock tissue.

14. The multi-residue method ("MRM") for testing equine tissue is not different from the MRM for cattle, swine, or poultry tissue. The MRM detects up to 52 analytes[4] in muscle, kidney, and liver. The drug residues being assessed include those of potential public health concern from all livestock, including equines.

[4] An analyte is a specific chemical residue undergoing analysis.

15. Because FDA has not established tolerances for drug residues in equines destined for use as human food, FSIS will enforce a zero tolerance standard. That is, any detection of a drug residue in an equine carcass sample will result in the carcass being condemned and designated as inedible. Every equine carcass sample will be submitted to an FSIS laboratory for analysis to identify whether the sample contains any of the 52 analytes. In contrast, other livestock species are tested differently, in that the sample is first screened for possible antimicrobial residues at the slaughter facility using a screening test and then is sent to one of FSIS's laboratories for confirmatory of the 52 analytes. In-plant samples that screen negative are not sent forward for confirmatory testing in the FSIS laboratories. FSIS expects that many of the drugs used in equines are not antimicrobials and therefore would not be detected by the in-plant antibiotic residue screening test. The laboratory confirmatory testing methods can discern antimicrobials and other residues of public health concern, such as phenylbutazone.
16. FSIS will also conduct intensified random drug residue testing of healthy appearing equines. Normally, healthy appearing livestock are not targeted for inspector-generated drug residue testing. Currently FSIS conducts intensified testing of veal calves and show animals. This is because the veal industry has a well-established history of improper drug treatment, and show animals have a higher likelihood of being subjected to illegal drug use in order to make them appear more muscular and desirable for judging purposes than untreated livestock. Because FSIS recognizes that most equines presented for slaughter will likely not have been raised initially for human consumption, FSIS has instructed its inspectors to randomly test healthy appearing equines at least the same rate as for show animals. *See* FSIS Directive 6130.1, ECF No 22-3. The frequency amounts

to sampling of approximately a minimum of four to ten percent of the number of healthy-appearing equines slaughtered each slaughter shift. However, FSIS inspectors may increase the frequency of residue testing, up to 100%, based on the establishment's compliance history. In addition, inspectors have been instructed to sample and test every equine when ante-mortem or post-mortem findings suggest an increased likelihood of recent drug treatment, including all equines that have a visible injection site.

17. I have attached to my declaration as Attachment 1, a chart showing the classes of drugs for which FSIS tested horses from 1997 through 2006, pursuant to the NRP, and the number of positive results relative to the total number of tests conducted for each drug class per year. This chart shows that the number of positive results for each class of drug was exceedingly low, rarely exceeding more than one per year for all drug classes except antibiotics. This chart also shows that FSIS tested for phenylbutazone from 1999 through 2000 and from 2003 through 2005, and that it never had more than one positive test result in each of those years. As previously noted, FDA has set no tolerances for any drugs that are applied to horses, so FSIS applies a zero tolerance standard to those drugs. Therefore, any carcass that tests positive for these drugs is condemned and cannot be sold in commerce as human food. In a Federal Register Notice, 65 Fed. Reg. 70,809 (Nov. 28, 2000), FSIS told establishments that if their HACCP plans include residue controls that constitute the best available preventive practices for slaughter establishments, if they implement those controls effectively, and if they supply FSIS with information about violators, then FSIS will not write a non-compliance record for violative residue findings that are followed by appropriate corrective actions. 9 C.F.R. § 417.3. In the absence of appropriate preventive controls, FSIS would issue a non-compliance record to the

establishment. Such an action could lead to progressively stronger enforcement that could result, ultimately, in withdrawal of inspection from the facility until such time as the establishment is able to proffer effective preventive controls. There is no reason to believe that the number of positive results for phenylbutazone or any other drug that is administered to horses is likely to be any higher now than it was from 1997 through 2006.

18. The intensified random drug residue testing program serves as a deterrent to abuse regarding drug treatment. Since each livestock carcass tested for a drug residue is required to be retained and unprocessed for nearly a week until the sample results are known, secured cold storage space for the carcasses must be provided by the establishment. The more carcasses sampled daily, the greater the space that is required. The establishment is required to make available to FSIS the name of the seller of livestock. 9 C.F.R. § 320.1. As with other livestock species, FSIS will publish a listing of suppliers of equines to slaughter establishments who have multiple positive test results for drug residues.

19. In addition to FSIS's residue testing program, each equine slaughter facility must include in its HACCP plan the measures that it will take to ensure that it does not produce meat containing residues that would result in adulterated product.

20. I am aware of the allegations in Plaintiffs' Motion for Preliminary Injunction regarding the water quality violations and other environmental harms associated with commercial horse slaughter operations at Dallas Crown in Kaufman, Texas, BelTex Corporation in Ft. Worth, Texas, and Cavel International in Dekalb, Illinois, prior to 2006. *See* Pls.' Br. in Support of Mot. for Preliminary Injunction ("Pls. PI Br."), ECF No. 16 at 4-5. Dallas

Crown, BelTex, and Cavel all initially discharged their waste water into their respective municipal waste water systems but Cavel later contracted with a professional environmental waste management company to remove inedible material, whereas the two horse slaughter establishments that recently received grants of federal inspection, Valley Meat and Responsible Transportation, discharge into septic tanks and lagoon systems that are wholly located on their premises, as discussed in their respective Decision Memoranda, ECF No. 22-4, 22-5. Therefore, the situations regarding discharge at Dallas Crown, BelTex, and Cavel are very different from those at Valley Meat and Responsible Transportation and any attempt to predict what might occur at the latter two plants based on the experiences of the former three is highly speculative.

21. In addition, both Dallas Crown and BelTex closed in early 2007, and Texas State law makes it illegal to sell, offer for sale, or exhibit horse meat as food for human consumption or to possess it for that purpose. Tex. Agric. Code Ann. § 149.002. Therefore, it is unlikely that Dallas Crown and BelTex will re-open and FSIS does not expect to receive any applications for grants of federal inspection of commercial horse slaughter from any such plants located in Texas. The Cavel plant also ceased operations in 2007 after the State of Illinois passed a law in May, 2007, that prohibits the slaughter of horses for human consumption, as well as the purchase, sale, importation, and exportation of horse meat for that purpose. 225 ILCS 635/1.5(a-b). Therefore, it is unlikely that Cavel will re-open and FSIS does not expect to receive any applications for grants of inspection from any commercial horse slaughter plant located in Illinois.

22. Plaintiffs' brief in support of their motion for the preliminary injunction cites several studies in support of their claim that chemical residues that allegedly are present in horse

tissues are likely to contaminate the environment in and around horse slaughter plants. Pls. PI Br. at 16-18. These studies are inapposite because all of them concern the land application of animal manure from large livestock production facilities that discharge into waste water treatment facilities. In contrast to livestock production facilities[5], commercial horse slaughter plants do not maintain large concentrations of horses for extended periods of time and thus do not generate the level of manure that is normally associated with livestock production. Horses are not expected to be present at the slaughter plant for more than a few hours immediately prior to slaughter because the humane handling requirements apply once the transport vehicles carrying the horses pass within the borders of the inspected facility. Horses present for more than 24 hours must have access to feed. Large quantities of undigested food in the digestive tract during the slaughter dressing process cause rupture of the lining of the digestive tract and contamination of the carcass with pathogens. Slaughter operations typically are reluctant to risk injury to the livestock that are held in pens designed for temporary holding.

23. Furthermore, as previously noted, the commercial horse slaughter plants that recently received grants of federal inspection do not discharge into waste water treatment facilities. Rather, Valley Meat uses a primary wastewater retention structure and lagoons to treat and dispose of its wastewater and effluent, and on June 14, 2013, it provided the Administrator of FSIS with an attestation that its horse slaughter operations will not result in any discharge into any navigable waters as defined by the Clean Water Act

[5] Large livestock producers and other concentrated animal farm operations are regulated by the EPA and its state and local counterparts.

("CWA").[6] Responsible Transportation also discharges waste water into lagoons located on its premises, after which it land applies the treated waste water pursuant to an Operation Permit for a Land Application System issued to it by the Iowa Department of Natural Resources on March 1, 2013.[7] Therefore, studies that analyze the waste water contamination associated with large livestock production operations are not accurate indicators of what might occur at the much smaller commercial horse slaughter operations. Importantly, the discharge material from the slaughter operation that is expected to be discharged into the primary wastewater retention structure and lagoons will be the water used to wash down the holding pens of the live equines, and from the water and antimicrobial treatments used to wash the carcass and to control pathogen during the slaughter operation. The blood and other bio-material from the slaughter operation will not be discharged into the primary wastewater retention structure and lagoons. Rather, this material will be diverted to the containers designated for inedible material. This inedible material is typically denatured prior to removal from the establishment, en route to the off-site rendering operation, to ensure that the material is

[6] Valley Meat also provided the FSIS with a copy of a National Pollution Discharge Elimination System ("NPDES") Form 3510-11, No Exposure Certification for Exclusion from NPDES Storm Water Permitting, dated May 10, 2013, which it also submitted to EPA pursuant to section 402 of the CWA, 33 U.S.C. § 1342, and its accompanying regulations. *See* 40 C.F.R. § 122.26(g). This form notifies that EPA that Valley Meat does not require permit authorization for its storm water discharges associated with industrial activity.

[7] According to this permit, "wastewater from the facility is treated in a lagoon system consisting of an anaerobic lagoon and two aerobic storage lagoon cells. The treated wastewater is disposed of by land application using a center pivot irrigation system. . . . No discharge to a water of the state from the storage lagoon or the land application area is permitted." The permit also imposes operational conditions, one of which is, "Wastewater shall not be applied within 300 feet of a continuous flowing stream or any physiographic feature that may provide direct connection to the groundwater."

not used for edible purposes. This handling of the inedible material by the equine slaughter establishments is comparable to other livestock slaughter establishments.

24. I am aware of the allegations in Plaintiffs' Motion for Preliminary Injunction regarding environmental hazards associated activities at the Valley Meat Company facility in 2010-12, while Valley Meat operated as a cattle slaughter facility. Pls. PI Br. at 6-7, 20-21. As noted in Decision Memorandum, ECF No. 22-4, on January 22, 2010, FSIS asked the New Mexico Environmental Department's ("NMED") Solid Waste Bureau to investigate a large compost pile of cattle offal and other inedible parts that the plant was maintaining just off the slaughter plant's official premises. On August 2, 2012, NMED initiated an administrative action against Valley Meat seeking an Administrative Compliance Order directing it to immediately cease offal composting operations and giving it 30 days from the receipt of the order to present NMED with an abatement plan addressing clean-up and removal of the previously composted material, as well as the disposition of any on-site offal that was being stored or actively composted at Valley Meat on the date of the order. In November 2012, NMED and Valley Meat settled the administrative action with a Final Stipulated Order that required Valley Meat to develop a plan for removing the compost pile and taking it to a landfill or other approved site within 45 days and imposed a civil penalty. Valley Meat paid a civil penalty in January 2013, and NMED terminated the enforcement action. Valley Meat currently does not have a composting permit from NMED, as required by N.M. Code R. 20.9.3.27, and thus is not authorized under the New Mexico law to compost any waste materials generated by its slaughter and processing activities. It has contracted with an inedible rendering company to pick up and dispose of inedible and condemned materials produced by commercial horse slaughter activities.

FSIS will post a notice on the inspection office bulletin board alerting agency inspectors that composting solid waste at Valley Meat is prohibited, that the inspectors should routinely verify that such activity is not occurring, and that they should notify NMED immediately if they observe composting on Valley Meat's premises. FSIS inspection personnel are required to be present daily when any federally inspected establishment is slaughtering or processing amenable product, including equines. Such establishments are afforded inspection service, without charge, up to eight consecutive hours per shift during the basic workweek. 9 C.F.R. § 307.4. Thus, FSIS inspection personnel would know if inedible waste is being composted in the immediate area surrounding the establishment.

25. Based on representations from Valley Meat, FSIS estimates that approximately 3,630 horses may be slaughtered on a monthly basis at its facility, for an approximate total of 43,560 horses per year. Based on similar representations from Responsible Transportation, FSIS estimates that approximately 800 horses may be slaughtered on a monthly basis at that facility once it reaches full production, for an approximate total of 9,600 horses per year. Therefore, FSIS expects the total number of horses slaughtered at both plants to be approximately 53,160 horses per year. This level of slaughter is closer to the lower end of the range of commercial horse slaughter that occurred at Dallas Crown, BelTex, and Cavel from 2001 through 2005, when all three plants combined slaughtered between 39,880 horses (2002) to 94,037 horses (2005) per year. During the same five-year period, annual commercial slaughter of all other amenable species ranged from 124,999,009 animals (2002) and 139,895,578 (2005) per year. At its peak in 2005, horses represented only 0.067 percent of the total number of livestock commercially slaughtered in the United States. FSIS estimates that approximately 148,568,527 non-

equine livestock were commercially slaughtered in the United States in 2012. FSIS further estimates that the majority of these non-equine slaughter establishments that slaughter more than 1,000 head per year also use primary wastewater retention structures and lagoons to treat and dispose of their wastewater and effluent. Assuming that there will be similar levels of commercial slaughter in 2013 and 2014, the horses projected to be slaughtered at Valley Meat and Responsible Transportation will comprise only 0.036 percent of all commercial slaughter in the United States in those years. If the total volume of commercial livestock slaughter in the United States does not result in the types and levels of environmental harms that Plaintiffs allege invariably accompany commercial horse slaughter, then, in my expert opinion, based on the anticipated levels of horse slaughter at Valley Meat and Responsible Transportation and considering how inedible and water waste material is proposed to be handled at these facilities, commercial slaughter at those plants cannot and will not result in the harms alleged and to the extent alleged. See ECF No. 22-4, 22-5.

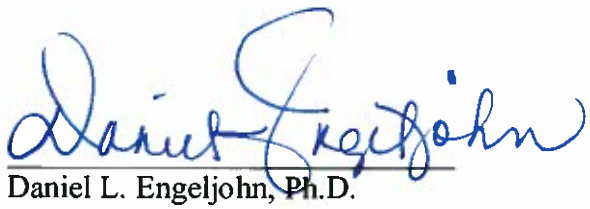
26. I am aware that Plaintiffs allege that residues of certain drugs that are used on horses remain in the tissues of horses for the lifetime of the horse and that these drug residues present both food safety and environmental hazards. FDA is the federal agency that is tasked with evaluating and approving all new animal drugs and setting tolerances for those drugs. FDA's drug approval process includes a NEPA analysis of how the environment will be affected by an animal drug after it is approved. See, for example, FDA's 2009 approval of the oral administration of phenylbutazone to horses subject to a categorical exclusion. 74 Fed. Reg. 1,146 (Jan. 12, 2009). *See also* 72 Fed. Reg. 60,550 (Oct. 25, 2007) (FDA's 2007 approval of the topical application of a

phenylbutazone paste to horses subject to a categorical exclusion); http://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm219207.htm

27. I have reviewed the Exhibits filed in support of Federal Defendants' Brief in Opposition to Plaintiffs' Motion for Preliminary Injunction and I do hereby certify that each of the aforementioned exhibits is a true and correct copy of a document in FSIS's official custody.

I declare under penalty of perjury in accordance with 28 U.S.C. § 1746 that the foregoing is true and correct.

Executed on July 19, 2013.



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ATTACHMENT 1

Scheduled Sampling Program: NRP_Horse

NRP Year	Chemical Analyses/Positive Test Results[Ω]						
	AvermectinsΦ	CHC/COPs	Arsenic	Sulfanamides*	Antibiotics*[2]	Phenylbutazone	Flunixin
1997	256/1	457/5	87/0	234/1	386/20	N/A	
1998	292/2	467/0	91/0	226/0	442/20	N/A	
1999	237/0	301/0	N/A	285/0	446/0	301/1	
2000	285/2	285/1	N/A	224/1	434/66	285/1	
2001							
2002							
2003	149/0	157/0	N/A	199/0	193/0	157/0	
2004*[3]	17/0	15/1	N/A	17/0	15/2	15/1	5/0
2005	76/0	78/0	N/A	N/A	76/0	78/0	
2006	113/0	281/1	N/A	N/A	112/0	N/A	

Ω: A positive test result refers to the detection of a chemical compound (1) at a level in excess of an established tolerance or action level set by FDA or EPA or (2) for which no tolerance or action level has been established

Φ: Ivermectin (1997, 1998)/Avermectin & Milbemycons (2000, 2003, 2006)

*: Sulfachlorpyridizine; Sulfadimthoxine; Sulfamethazine; Sulfathiazole

*[2]: Bacitracin; Chlortetracycline; Erythromycin; Gentamicin; Hygromycin; Neomycin; Oxytetracycline; Penicillins; Novobiocin; Streptomycin; Tetracycline; Tylosin

*[3]: Specially designed exploratory sampling for equine tissue was conducted in 2004 in order to better assess compliance with expectations for export of equine products to Europe

N/A: Not assessed