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April 6, 2012

VIA FEDERAL EXPRESS

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
George Washington Carver Center, Rm. 2-2127
5601 Sunnyside Ave.
Beltsville, MD 20705-5272

Re: Petition to Create Rules and Regulations Governing the Sale, Transport and Processing of Horses and Horse Meat Intended for Human Consumption

Dear Sir or Madam:

Enclosed please find a Petition for Rulemaking, directed to the Food Safety and Inspection Service and United States Department of Agriculture. As detailed in the Petition, Petitioners request that the agencies create rules and regulations governing the sale, transport and processing of horses and horse meat intended for human consumption.

Please note that Petitioners request expedited review of this Petition, because the action requested by Petitioners is "intended to enhance the public health by removing or reducing foodborne pathogens or other potential food safety hazards that might be present in or on meat," specifically horse meat. 9 C.F.R. § 392.8(a). The Petition and its supporting documentation, including but not limited to Exhibit 1 to the Petition, contains extensive scientific information "that demonstrates that the requested action will reduce or remove foodborne pathogens or other potential food safety hazards that are likely to be present in or on [horse] meat." *Id.* § 392.8(b).

Based on the foregoing, Petitioners request that FSIS review this Petition ahead of other pending petitions.

Sincerely,

Bruce A. Wagman

BAW:lfl

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PETITION

To Create Rules and Regulations Governing the Sale, Transport and Processing of Horses and Horse Meat Intended for Human Consumption

Before the United States Department of Agriculture
United States Food Safety Inspection Service

April 9, 2012

To:

Docket Clerk,
U.S. Department of Agriculture
Food Safety and Inspection Service
George Washington Carver Center, Room 2-2127
5601 Sunnyside Avenue
Beltsville, MD 20705-5272

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On behalf of
FRONT RANGE EQUINE RESCUE
HUMANE SOCIETY OF THE UNITED STATES

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I. INTRODUCTION

Front Range Equine Rescue ("FRER") and The Humane Society of the United States ("HSUS") (collectively "Petitioners") petition the United States Food Safety and Inspection Service ("FSIS"), an agency of the United States Department of Agriculture ("USDA"), pursuant to the requirements for such petitions under the Federal Meat Inspection Act, 21 U.S.C. § 601, *et seq*. ("FMIA"), its accompanying regulations, 9 C.F.R. §§ 300, *et seq*., and the Administrative Procedure Act, 5 U.S.C. § 553(e). Petitioners request the Secretary of the USDA, Tom Vilsack, and the Office of the FSIS Administrator, Alfred V. Almanza, to classify all horses who were formerly companion animals, wild horses, or work and sport horses (involved in ranching and competitions, including rodeos and racing), and any other horses without a proven lifetime medical history, as "Condemned" and adulterated, and unusable for the production of horse meat for human consumption. Petitioners also request that the FSIS engage in administrative rulemaking regarding horses intended for human consumption, in order to prevent against the risk that consumers of horse meat will have painful or prolonged adverse reactions or drug side effects, or contract serious, contagious, or fatal diseases, after they have eaten the meat of horses sent to slaughter, and to ensure that proper controls are in place to prevent horses whose meat would be adulterated from being slaughtered for food. Petitioners make this request because of the very real potential for consumers to experience such severe side effects and adverse reactions, unless adequate screening and verification demonstrates that the horses have not been exposed to any drugs, treatments or other substances that create the possibility of such problems.

In November 2011, after a roughly five-year period in which inspection of horses for slaughter for human consumption was prohibited, the FSIS was once again authorized to inspect horses destined for slaughter. If horse slaughter for human consumption begins in America, the horses' carcasses, if allowed to pass FSIS inspection, will eventually be sold as meat for human consumption in America and abroad. Historically, almost all horses who have been slaughtered for use as human food started their lives in one of three situations – as companions living with families across America and used for pleasure, recreation and work; as sport horses (involved in,

among other things, jumping, vaulting, racing, rodeos, dressage and other competitive activities); or as wild horses on the public and private lands. These animals are not raised for food in the way other animals, such as cows, pigs and chickens are, who from before conception are maintained within a regulated industry. The horses, throughout their lives, are not monitored or controlled by an agricultural industry aware of the legal restraints placed on the presence of contaminants in food animals. They have almost certainly ingested, or been treated or injected with, multiple chemical substances that are (1) known to be dangerous to humans if eaten, (2) untested on humans, or (3) specifically prohibited for use in animals destined to be slaughtered and turned into meat. These substances to which the horses have been exposed create the potential for great danger to humans if they are eaten. The presence of these substances in horse meat may cause a plethora of health problems, from the transient to the fatal, the acute to the chronic. Exposure to these substances puts consumers at the risk of cancer, life-threatening autoimmune diseases, or other illnesses of significant proportion.

The pharmacological history of horses turned into meat, and therefore the potentially toxic nature of the meat from those horses, is almost completely unknown. The horses are often sold from owner to auction and eventually, unbeknownst to the original owners, to slaughter by "killer-buyers" who have purchased them at auctions and from other sources, and then sell them to slaughterhouses. When the horses are finally transported and sold for slaughter, there is virtually no way to determine what substances they have been treated or injected with, or that they have eaten, over the course of their lives.

One thing is certain, though. Tainted by prohibited drugs and chemicals, horse meat from American horses is "adulterated" under the FMIA, and thus must be kept out of the food supply.[1] Since 1907, the FMIA has been focused on protecting the health and welfare of meat consumers and eliminating the harm caused by adulterated food.[2] The FSIS is responsible for

[1] 21 U.S.C. § 601(m).

[2] *Id*. at § 602.

inspecting meat under the FMIA and enacting regulations to carry out that authority.[3] Horses loaded up with dangerous and prohibited drugs must be stopped at the slaughterhouse gates, in order for FSIS to honor the language and spirit of the FMIA. Otherwise, FSIS will be sanctioning the dissemination of adulterated meat containing harmful additives with the potential for significant consumer harm.

The focus for FSIS is on the animals, and their flesh when it is turned into meat, and the condition of horses going to slaughter clearly fits within the FSIS definition of "adulterated" meat.[4] The horses themselves are laced with sufficient foreign and potential toxic substances so that their meat should never satisfactorily pass any inspection that complies with the FMIA. Exhibit 1 to the Petition, "Banned And Dangerous Substances Commonly Given To Horses Sent To Slaughter," provides a nonexhaustive list of examples of drugs and other substances to which American horses are routinely exposed throughout their lives, through injection, ingestion or topical application.[5] Exhibit 1 includes (1) drugs that expressly prohibited (by law or by label) from use in food animals; (2) drugs and other substances that are known to be harmful to humans when eaten; and (3) drugs and other substances that have never been tested in humans, so that the potential dangers from ingestion of horse meat laced with the residue of these substances creates a frightening unknown possibility of medical consequences. It is important for the agency and the public to appreciate that the substances listed on Exhibit 1 are only illustrations of some of the more commonly used drugs and additives that may potentially be lurking poisons in horse meat. There are multiple products and brand name compounds that may incorporate many of the items listed on Exhibit 1.

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[3] *See*, *e.g.*, 7 C.F.R. §§ 2.53, 2.7; 9 C.F.R. § 300.2.

[4] *See*, *e.g.*, 9 C.F.R. § 301.2(2)(iii) (meat with unsafe food additives is adulterated); 9 C.F.R. § 318.20 (meat with unapproved animal drug residues is adulterated).

[5] *See* Exhibit 1; Declaration of Hilary Wood ("Wood Dec."), attached hereto as Exh. 2, ¶¶ 6-7; Declaration of Peggy W. Larson ("Larson Dec."), attached hereto as Exh. 3, ¶ 7; Declaration of Joanne Pavlis ("Pavlis Dec."), attached hereto as Exh. 4, ¶¶ 4-5; Declaration of Randy Parker, D.V.M. ("Parker Dec."), attached hereto as Exh. 5, ¶¶ 7-9.

This situation is solidly within FSIS jurisdiction, and current FSIS regulations do not address the very real problem of horse meat, because procedures established for the inspection of other food animals cannot determine the presence of the multitude of prohibited drugs and potentially dangerous substances given to American horses during their lifetime. FSIS should be aware of the potential for drastic consequences from humans' ingestion of meat from these animals.

The chance of tragic human reactions should guide the agency's decisionmaking process with respect to the use of horses for human consumption. Because there is no realistic way to fully assess the risks of eating horse meat, and because all horse meat is potentially dangerous in many ways, there is no other course than for the FSIS to ban the sale of horse meat from American horses, unless the agency can reach a level of certainty about the substances these horses have eaten or to which they have been exposed. Petitioners are doubtful that the FSIS can invoke rules that will provide the level of certainty needed for American horses to be turned into meat, but have provided a list of proposed rules that, if placed in effect and fully enforced, could meet that challenge.

II. INTERESTS OF THE PETITIONERS

Petitioner FRER is a Colorado-based nonprofit group incorporated under Section 501(c)(3) of the Internal Revenue Code. FRER is dedicated to stopping cruelty and abuse of horses through rescue and education.[6] FRER is actively involved in the rescue, rehabilitation and adoption to good homes of domestic and wild horses found at auctions and horses destined for slaughter; and in educational efforts regarding responsible horse ownership, the cruelty of horse slaughter and wild horse roundups.[7] FRER has assisted thousands of horses through its rescue and educational programs.[8] While some of FRER's horses are surrendered by their

[6] Wood Dec., Exh. 2, ¶ 2.

[7] *Id.*

[8] *Id.*

owners or rescued when abandoned, many are rescued from livestock auctions; others are purchased at feed lots before they are sent to slaughter.[9]

Petitioner The Humane Society of the United States (HSUS) is a non-profit organization that promotes the protection of all animals.[10] The HSUS maintains its headquarters in Washington, DC and is the largest animal protection organization in the United States, with more than eleven million members and constituents.[11] The HSUS actively advocates against practices that injure or abuse horses and opposes the slaughter of horses for human consumption.[12] The HSUS has been actively involved in litigation and the support of legislation directed at the prohibition of horse slaughter and the transport of horses for slaughter.[13] Furthermore, the HSUS offers information regarding the inhumane treatment of animals on a wide spectrum of topics, including the process of slaughtering horses for their meat.[14]

III. ACTION REQUESTED[15]

Based on the facts and law presented here, Petitioners request that the FSIS issue a rule that renders any horse "U.S. Condemned" for use as food for human consumption, unless the slaughterhouse (or its agent) receiving or buying the horse obtains (1) an accurate record of all of the horse's prior owners, (2) a record of all drugs, treatments and substances administered to the horse since birth, and (3) verification that the horse has at no time been exposed to any substances prohibited for use in animals intended for use as food. Petitioners also request that,

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[9] *Id.*

[10] Declaration of Keith Dane, attached hereto as Exh. 7, at ¶ 2.

[11] *Id.*

[12] *Id.* ¶ 3.

[13] *Id.* ¶ 4.

[14] *Id.*

[15] On March 27, 2012, Petitioners filed a Petition with the Department of Health and Human Services and the Food and Drug Administration ("FDA"), requesting the FDA to enact certain rules and regulations regarding horses and horse meat intended for human consumption. *See* FDA Docket Number FDA-2012-P-0299-0001/CP. The prior Petition requests separate actions based on different legal authority under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*, and FDA regulations under that law. The acts and rules requested in this Petition are solely within the jurisdiction of the FSIS, separate and apart from any FDA action, and are necessary regardless of the FDA's response to the prior Petition.

for any horses that do satisfy those three criteria, the FSIS adopt rules and regulations that mandate the testing of the flesh and organs of all such horses going to slaughter. The required tests should examine the horses for all substances listed on Exhibit 1 to the Petition, unless such substances have been subjected to sufficient human testing to ensure no danger in ingestion of that substance to any human.

Because of the elevated chance that these horses have been exposed to a myriad of substances prohibited for use in food animals, the only way to protect the food supply and the consuming public is for the FSIS to be able to provide this level of reassurance. Based on the Factual and Legal Background and Statement of Grounds below, Petitioners request that the FSIS adopt the following regulations:

1. Certification of Horse Meat as Approved. No horse or horse meat shall be approved for human consumption in America, or for export intended for human consumption elsewhere, unless the following criteria are all met: (1) Written records shall accompany the horse or horse meat attesting to the ownership of the horse at all times from birth until the horse's death; (2) Written records shall accompany the horse or horse meat that provide a complete list of all drugs, treatments and other substances that have been administered to the horse during the course of the horse's life, from birth until the time of the horse's death, in connection with any medical care, prophylactic treatment of diseases, vaccination, pest control, growth promotion or regulation, reproductive or hormone therapy, including but not limited to all prescription and over-the-counter medications, pain medication, sedatives, anesthetics, antibiotics, hormones (synthetic or natural), steroids, dewormers, fly or pest sprays, ointments, liquids or applications; (3) Prior to slaughter, an FSIS inspector shall review the written records accompanying each horse intended for slaughter for human consumption and verify that no prohibited or potentially dangerous substances have been administered to the horse during the course of the horse's life, from birth until the time of certification or the horse's death.

2. Potentially Dangerous Substances in Horse Meat. All substances, including "new animal drugs" and other veterinary drugs, shall be considered "potentially dangerous substances"

if there is scientific evidence that ingestion of horse meat containing these substances, by any significant percentage of the human population, could cause detrimental health consequences to that group of individuals.

3. Unqualified Horses or Horse Meat. Any horse meat or horse intended for human consumption shall be labeled and certified as "U.S. Condemned," if all the criteria listed in 1. above are not met. "U.S. Condemned" horses and horse meat shall be prohibited from sale or transport to slaughter for human consumption, and labeled as such. Any horse determined to be "U.S. Condemned" under this rule shall be returned to the transporter.

4. Testing of Horses and Horse Meat. Any horse or horse meat intended for human consumption, and that meets all the criteria listed in 1. above, shall be tested for the presence of all potentially dangerous substances in a manner that ensures discovery of the presence of any residue of any potentially dangerous substances in the horse or horse meat. If any potentially dangerous substance is found, or if testing is not available to determine the presence of any prohibited substances, the horse or horse meat shall be certified as "USDA Condemned," and labeled as such.

5. Destruction of Unqualified Horse Meat. All horse meat that is labeled and certified "USDA Condemned" shall be safely decontaminated and disposed of in a manner that ensures it does not contaminate the environment.

IV. FACTUAL BACKGROUND

A. Americans Love Horses.

Americans have a long relationship with horses. From parades, search and rescue teams, and competitions to police and military support, advertisements, and summer camps, Americans use horses for a vast array of purposes. We keep them as companions. They have stood by, loyal as dogs, during every war from the American Revolution up to the present day. They shoulder the burdens to work for farmers and ranchers. We cheer them on as they race and watch them in the Olympics. We admire their wildness and herd cultures where they are left alone in nature on the open range.

There are approximately nine million horses in the U.S. and two million horse owners,[16] and tens of thousands of wild horses. Of the nine million owned horses, a 2005 study concluded that almost four million are used for recreation, three million for "showing," eight hundred thousand for racing, and two million for activities ranging from farm and ranch work to police work and rodeos.[17] A 2007 study by the federal government found that almost forty-six percent of horses are used for pleasure, twenty-five percent for farm and ranch work, sixteen percent for breeding, and ten percent for show and competition.[18]

B. American Horses Are Not Intended to Be Meat.

One purpose horses do not currently serve in America is as a source of meat.[19] Because of the way Americans treat their horses – as companions, sources of recreation, and tools of labor – they neither raise horses for human consumption nor consume horse meat. Americans treat their horses more like their dogs and cats than other commercial animals. They give them whatever drugs and substances they need to keep them healthy, strong, and free of pests. Horses' place in American culture makes their slaughter something that, so far, has never received much support.

Nevertheless, when Americans have lost interest in their horses (whether companions, competitors, or racehorses), or when we capture the wild horses on public land, the profiteers buy them and send them off to be killed. Horses are transported to Canada and Mexico, where they are slaughtered, butchered, and their meat eaten. Horse meat is a common food, even a

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[16] Study by Deloitte Consulting LLP for the American Horse Council Foundation (2005), http://www.horsecouncil.org/national-economic-impact-us-horse-industry (attached hereto as Exh. 8).

[17] *Id*.

[18] USDA Animal and Plant Health Inspection Service Info Sheet (Mar. 2007), http://www.aphis.usda.gov/animal_health/nahms/equine/downloads/equine05/Equine05_is_Demographics.pdf (attached hereto as Exh. 9).

[19] *See, e.g., Cavel Int'l., Inc. v. Madigan*, 500 F.3d 551, 545 (7th Cir. 2007) ("Americans do not eat horse meat. . . ."); *see also* Terry L. Whiting, *The United States' prohibition of horse meat for human consumption: Is this a good law?,* 48 CANADIAN VET. J. 1173, 1174 (Nov. 2007) ("A commercial market for horse meat as food has never emerged in the USA."), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2034431/ (attached hereto as Exh. 10).

staple, in many regions, from China to Southeast Asia to Europe.[20] It regularly appears on menus and in markets. Between 100,000 and 200,000 American horses, from a variety of sources, are slaughtered outside of the United States and end up in restaurants and markets each year, and hundreds of thousands of people are eating American horse meat annually.

Because Americans view horses as somewhat totemic or "sacred" animals, horse slaughter for human consumption is overwhelmingly unpopular in the U.S.[21] A January 2012 poll confirmed that eighty per cent of Americans are strongly opposed to horse slaughter.[22] The survey found that "Americans oppose horse slaughter overwhelmingly regardless of their gender, political affiliation, whether they live in an urban or rural area, or their geographic location," or whether they own horses themselves.[23]

Americans revere horses and oppose horse slaughter and consumption for a variety of reasons. Some attribute this opposition to culture.[24] Others attribute it to the role of horses in American history, from the founding era to westward expansion.[25] Another factor deterring American consumption of horse meat is the level of animal cruelty connected with the slaughter

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[20] *Id*. at 552.

[21] Christa Weil, *We Eat Horses, Don't We?*, NY Times, March 5, 2007 ("*Weil*"), www.nytimes.com/2007/03/05/opinion/05weil.html (attached hereto as Exh. 11); Josh Ozersky, *The Case for Eating Horse Meat*, TIME (Dec. 28, 2011), http://ideas.time.com/2011/12/28/the-case-for-eating-horse-meat/ (attached hereto as Exh. 12).

[22] http://www.prnewswire.com/news-releases/aspca-research-confirms-americans-strongly-oppose-slaughter-of-horses-for-human-consumption-138494089.html ("*ASPCA Survey*") (attached hereto as Exh. 13); *see also* Press Release, The Humane Society of the United States, USDA Threatened with Suit if Court Order Not Followed Before Horse Slaughter Resumes (Feb. 3, 2012) *available at* http://www.humanesociety.org/news/press_releases/2011/11/usda_threatened_02032012.html (attached hereto as Exh. 14).

[23] *ASPCA Survey*, *supra* Note 22.

[24] Nicholas Day, *They Eat Horses, Don't They?*, CHOW (Nov. 17, 2006), http://www.chow.com/food-news/53692/they-eat-horses-dont-they/ (attached hereto as Exh. 15); Dan Flynn, *Horse Slaughter Issue Won't Go Away* (Oct. 25, 2011), http://www.foodsafetynews.com/2011/10/horse-slaughter-issue-wont-go-away/ (attached hereto as Exh. 16) (attributing Americans' opposition to eating horse meat to its "Cowboy Culture").

[25] Brian Palmer, *The Delicious Mr. Ed*, SLATE MAGAZINE (Oct. 24, 2011), http://www.slate.com/articles/health_and_science/explainer/2011/10/slaughtering_horses_for_meat_is_banned_in_the_u_s_why_.html (attached hereto as Exh. 17).

of horses, who are especially combative and frightened in slaughterhouses.[26] Yet others do not even attempt to explain their view, simply calling the eating of horse meat "repulsive[]" and "gross."[27]

Regardless of the rationale – from the "transcendent relationship" a rider forms with her horse to the popularity of movies like *Seabiscuit* and *War Horse* – Americans do not eat horse meat.[28] And they do not want their companions slaughtered and exported for others to eat either.

Americans did eat horses in decades past, but consumption has dropped off to almost nothing in the past thirty or forty years.[29] At this point, horse meat is almost never eaten in America. But because of recent legal changes (discussed in this Petition) and a business desire to slaughter horses for profit, it may soon be served again in restaurants and homes across the nation, and American horses will continue to be shipped over our borders, north and south, for foreign markets.

Although meat from slaughtered American horses has been shipped overseas for years, American horses have never been bred, borne, or raised specifically as food animals. As described below, the horses who end up as meat come from varied backgrounds and have been exposed to a multitude of identifiable and unknown drugs, substances, and treatments that have been applied to, injected in, and ingested by the horses. Many of those substances may be dangerous or even fatal to humans who ingest them. When meat from horses who have been exposed to those substances is eaten, there is a real potential for extreme consequences.[30] Because of the impossibility of knowing these horses' histories, every bite of American horse meat includes the potential for death and disease for the consumer; the chance of liability for the

[26] *See* Larson Dec., Exh. 3, ¶¶ 11-21.

[27] *Weil*, *supra* Note 21.

[28] *Weil*, *supra* Note 21.

[29] *Cavel Int'l.*, *supra* Note 19, 500 F.3d at 552.

[30] *See* Larson Dec., Exh. 3, ¶ 8-11, 14, 16; Declaration of Michael Greger ("Greger Dec."), attached hereto as Exh. 6, ¶¶ 13-15.

manufacturer, producer and seller; and the corollary need for all involved government agencies to ensure the safety of horse meat to the greatest possible degree.

C. Horses Used as Food Come from Sources Where They Are Regularly Exposed to the Substances in Exhibit 1 to the Petition.

As discussed above, and as proven by the evidence submitted with the Petition, American horses who end up as meat almost all begin their lives in factual settings that do not contemplate their ultimate end. Horses who become meat are of all breeds and ages, though most of them are young and healthy.[31] The horses come from several sources that can first be split into two larger categories – carefully-maintained and cared-for, privately-owned horses; and wild horses, who then often become privately-maintained horses for some time before their sale at auction that sends them on to slaughter. Almost every American horse sent to slaughter fits into one of these categories.[32]

A majority of the horses for slaughter, who end up being bought at auction by "killer-buyers" (who often act as middlemen to the final auctioneer or stockyard), spend most of their lives in highly-managed, highly-medicated home and stable environments. Their lives, before their final weeks or months as commodities in the slaughter industry for meat production, are both privately controlled out of the public eye, and almost completely unregulated.[33] They are treated as pets or as valuable commodities, and they are therefore given a series of medications, and treated with a number of substances, identical or similar to those listed in Exhibit 1 and identified in the following section of the Petition. Some, but not all of these are *per se* dangerous

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[31] Larson Dec., Exh. 3, ¶ 22. The USDA has reported that 92.3 percent of horses arriving at slaughterhouses were in "good" condition. http://www.humanesociety.org/issues/horse_slaughter/facts/facts_horse_slaughter.html

[32] Larson Dec., Exh. 3, ¶¶ 20-21, 24-25.

[33] There are rules and regulations that limit the use of certain drugs in connection with some competitive use, but most of the substances listed on Exhibit 1 are approved for use in competitive horses. Competitive horses may be treated even with banned substances when they are not actively in competition. It is also the case that abuse of even prohibited drugs in the racing industry is an ongoing problem. Joe Drape, *At Breeders' Cup, a Volatile Mix of Speed and Drugs*, NY Times, Nov. 3, 2010 ("Numbers suggest there is, indeed, a culture in American horse racing that ultimately rewards those who seek any means, legal and otherwise, to gain an edge."), *available at* http://www.nytimes.com/2010/11/04/sports/04racing.html (attached hereto as Exh. 18).

to humans. All of the Exhibit 1 drugs may be harmful if ingested by at least some portion of the human population, and over the course of her life, each horse is exposed to likely hundreds of applications of drugs, substances and treatments that could lead to detrimental side effects in the humans who eventually eat them.

The use of many of these products cannot be avoided in caring for horses, and often the use of these substances is necessary to provide for the health, safety and comfort of the horses. The substances fall into a number of identifiable categories, each category including tens, if not hundreds, of individual generic or brand names, which are regularly and routinely used on American horses.[34] First, in order to control common pests such as flies, ticks and other insects, horses are regularly treated with a number of substances, either topically or systemically.[35] Many of these treatments are specifically labeled with a warning that the treatments should not be used on animals who are intended to be used for food.[36] Second, in order to treat many ailments and medical problems, horses are injected with medications, many of which also are banned from use in animals who will become meat.[37] Third, many horses are treated with antibiotic and antibacterial compounds that are banned for use in food animals, and that could have a variety of negative health impacts if ingested by humans.[38] Fourth, various hormones and

[34] *See* Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[35] Examples include butoxy polypropylene glycol (fly spray), di-n-propyl isocinchomeronate (fly control products), n-(2-ethylhexyl)-5-norbornene-2,3-dicarboximide (fly control), and N-Octyl Bicycloheptene Dicarboximide (fly spray). *See* Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[36] Examples include ponazuril (for treatment of equine protozoal myeloencephalitis) and eucalyptus oil (for dressing wounds). *See* Exhibit 1.

[37] Examples include moxidectin (a dewormer) and ceftiofur crystalline free acid (for treatment of lower respiratory tract infections). *See* Exhibit 1.

[38] *See Natural Resources Defense Council v. U.S. Food & Drug Administration*, No. 11 Civ. 3562 (THK), Memorandum Opinion and Order (Mar. 22, 2012) (granting summary judgment for plaintiff; noting that "[f]or over thirty years, the FDA has taken the position that the widespread use of antibiotics in livestock for purposes other than disease treatment poses a threat to human health"). Examples of antibiotics given to horses include entamicin sulfate solution (for the control of bacterial infections in the uterus and for improving conception), olaquindox (for growth promotion), and furazolidone (for treating wounds and sores). *See* Exhibit 1; Greger Dec., Exh. 6, at ¶¶ 11-12.

steroids are used on competition and companion horses for various reasons. Even where they are not expressly banned or even approved for human use, the ingestion of these substances could have dramatic effects on all humans, and especially on women of child-bearing age and the unborn.[39] Fifth, many over-the-counter medications used on horses are expressly banned, in federal regulations enacted by the Food and Drug Administration ("FDA"), from use in food animals – something the FDA would not have done without a concern about humans eating meat infected with those medications.[40] Sixth, many drugs that are approved for use on horses are specifically excluded from use in food animals, because of the need for all prescription drugs to be given under the direction and supervision of a physician.[41] It is a matter of common understanding that drugs of any kind, but especially prescription medications, should not be anonymously or secretly given to people.[42] But if those substances are in horse meat, that is exactly what will happen.

D. There are Over 110 Toxic Substances, Many Prohibited for Use in Animals Who Are Made Into Food – All of Which are Used on Horses.

The FSIS, the FDA, and private industry have recognized that many of the drugs, treatments and other substances that are regularly applied to, injected in or ingested by American horses create grave dangers if eaten by humans. Because of the possibility of unpleasant to fatal side effects, and the potential for crippling or chronic illnesses or even death that may result from ingestion of meat tainted with these toxic chemicals, literally hundreds of products are clearly labeled "Not for use in animals used for food" or "Not to be given to animals that will be eaten by humans" or some similar language.[43] The message is clear – once a horse (or any animal) has

[39] *See* Exhibit 1; Greger Dec., Exh. 6, at ¶ 13.

[40] It is illegal to administer over fifty of the drugs listed on Exhibit 1 to animals intended to be used as food. Exhibit 1 also includes citations to the corresponding Code of Federal Regulations sections, which exclude animals who have received those drugs from slaughter for human consumption.

[41] Examples include dimethylsulfoxide (to reduce swelling), xylazine (a common sedative used in veterinary medicine) and prednisone (an anti-inflammatory agent). *See* Exhibit 1.

[42] Greger Dec., Exh. 6, at ¶ 3.

[43] Exhibit 1 includes examples of many such drugs only with respect to horses.

been exposed to even one of these chemicals, the horse must be permanently excluded from any possibility of being used for food. They cannot be slaughtered for human consumption and their flesh cannot be turned into meat. This determination, whether made by the agency or by the industry, is a potent declaration that horse meat from horses who have had one of these substances may be dangerous, unhealthy, even deadly.

Exhibit 1 to the Petition is an illustrative, but not complete, list of substances that are routinely given to American horses – and proof positive of the inherent problems in horse meat. Virtually every single substance on the list is used on American horses who may end up as horse meat, sometimes routinely, sometimes by prescription.[44] And a majority of the substances on the list is actually banned for use on animals who will be consumed by humans – regardless of when, over the course of their lives, the horses were exposed to that substance. There is good reason for the bans, given the potential consequences from human ingestion. Petitioners provide illustrations below:

1. *Acepromazine* is used as a sedative and antiemetic in horses. Its use has been discontinued in humans. While it was previously used in humans, its ingestion can still be harmful or fatal, or cause neurologic symptoms.[45] Other sedatives have been expressly banned from use in horses who will become food, but they continue to be used by horse owners.[46]

2. *Acetazolamide* is a diuretic commonly used in horses, and appropriate for use in some humans.[47] However, for many humans, it can cause serious health consequences, up to and including death.[48]

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[44] *See* Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[45] See further detail included on Exhibit 1.

[46] *See, e.g.*, 21 C.F.R. § 522.2662 (xylazine, marketed as Anased, a sedative, is prohibited for use in horses who will become food, but its use on horses is allowed).

[47] Many drugs that are used by humans are also banned for use in animals who will be eaten. This may be because the drugs may be extremely dangerous to some humans, whether because of particular allergies/sensitivities or because they are taking other medications; because the drugs have not been tested on humans who take them orally; or because no tests have ever been done to see what byproducts of the drugs may end up in the meat of animals who take them. Since there is no way of filtering the consuming population to avoid adverse reactions, and no way to identify meat from animals who have had specific substances, the fact that a drug may be safe for some humans does not assure its safety for the consuming public.

[48] See further detail included on Exhibit 1; *Acetazolamide* (*sulfonamide*) is contraindicated in patients with hyperchloremic acidosis, angle-closure glaucoma, kidney and liver disease, and in

(Footnote continued on next page)

3. *Blue Kote* is a topical ointment, antiseptic, and protective wound dressing used by many horse owners. Its active ingredient is *acriflavine*. The Material Data Safety Sheet (MSDS)[49] for this substance states that it is "[h]azardous in case of . . . ingestion" and is "toxic to lungs [and] mucous membranes."[50]

4. *Adequan*, a commonly-used drug for degenerative and traumatic joint problems, and containing the active ingredient *polysulfated glycosaminoglycan*, cannot legally be given to horses used for food.[51] *Adequan* has never been tested on humans, so that its potential toxicity and adverse reactions to its use by humans are completely unknown.[52]

5. *Altrenogest* is the active substance in *Regu-Mate*, an artificial hormone and growth promoter. Even skin contact with the chemical is unsafe, and it is especially dangerous to pregnant women and women of child-bearing age, as it can disrupt biological function.[53] Unsurprisingly, the federal government has expressly forbidden its use in animals used for meat.[54]

6. *Amikacin* is used for the treatment of genital tract infections in mares. Use of *amikacin* has been expressly prohibited by law for "in horses intended for human consumption."[55]

7. Many different *antibiotics*, which help fight infection and the microorganisms that cause infection, are used in horses, in the companion, sport, and wild horse areas. While many of them are the same drugs used in humans, they are potentially dangerous to humans who either have allergies or sensitivities to them. Because of the unknown administration of antibiotics over the course of a horse's life, this problem cannot be avoided.[56] Additionally, the use of antibiotics in food animals, and the

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patients with Addison's disease. Many adverse side effects have been reported. *See* http://www.drugs.com/pro/acetazolamide.html.

[49] Material Safety Data Sheets are used in industries around the world to provide vital information about the safety, composition and other aspects of products on the market. They are generally considered conservative reports of the important information on a product, and are relied on by legislatures, courts, and administrative agencies.

[50] http://www.sciencelab.com/msds.php?msdsId=9927421. See further detail included on Exhibit 1.

[51] 21 C.F.R. § 522.1850.

[52] See further detail included on Exhibit 1.

[53] http://www.drugs.com/vet/regu-mate-solution.html.

[54] 21 C.F.R. § 520.48 ("Do not use in horses intended for human consumption."); see further detail included on Exhibit 1.

[55] 21 C.F.R. § 529.56; see further detail included on Exhibit 1.

[56] *See, e.g.*, 21 C.F.R. § 522.90c (Ampicillin Sodium: "Do not use in horses intended for human consumption."); *see also* http://www.drugs.com/vet/equifur-can.html (*Nitrofurantoin*, marketed as *Equifur* and used for bacterial infections of the urinary tract, "is not to be administered to horses that are to be slaughtered for use in food."); 21 C.F.R. § 524.1580b (*Nitrofurazone*, used as

(Footnote continued on next page)

subsequent ingestion by humans of those animals, has the potential to create antibiotic resistance in humans, which can cause significant problems for humans upon subsequent illness.[57]

8. *Antiseptic* compounds are often considered dangerous to humans upon ingestion, and are used regularly to clean horses' skin and wounds. Some of those substances are also expressly labeled to indicate that, as a matter of federal law, they cannot be used in animals who will become food.[58]

9. *Avermectin* is a common chemical component in dewormers used on American horses. Dewormers are part of typical routine care for most horses, in order to prevent worm infestation and the problems related with infestation. The MSDS for this substance directs that upon any human ingestion of the drug, immediate medical attention is required. The MSDS, like the label, also states without limitation that it is not to be used on horses who will be eaten.[59] The deworming products *Agri-mectin, Bimectin, Equell, Equimax, Exodus, Farnam Ivercare, Horse Health, Ivercare*, *Prometin E,* and *Zimecterin* all contain substances prohibited under federal law for use in "horses intended for human consumption."[60]

10. *Equipoise* is an injectable form of *boldenone undecylenate* and is used popularly to treat horses who are debilitated, in order to bolster their physical condition. When men use it (illegally), it has been known to cause blood dyscrasias, psychological aberrations, "sleeplessness, chills, vomiting, diarrhea, hypertension, [and] prolonged blood clotting time." When women use it, hormonal effects occur, including but not limited to menstrual irregularities and post-menopausal bleeding.[61] Probably because of all those potential problems, horses who have received the drug cannot be used for meat,[62] but its use on horses otherwise is legal.

11. *Butorphanol* is a commonly-used drug for pain relief in a wide variety of situations involving horses. Its effectiveness makes it a regular choice, but, probably because of its severe side effects (see Exhibit 1), federal law forbids the use or sale for human consumption of meat from any horse who has had it.[63]

12. *Carbadox* is a growth-enhancing antibiotic. If ingested, it can cause

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antibacterial on surface wounds but not "for use in horses intended for human consumption" – "Federal law prohibits the use of this product in food-producing animals.").

[57] Parker Dec., Exh. 5 at ¶ 7; see further detail included on Exhibit 1.

[58] *See*, *e.g.*, 21 C.F.R. § 524.402 (*Chlorhexidine* topical antiseptic not to be used on horses intended for human consumption); see further detail included on Exhibit 1.

[59] http://msds.farnam.com/m001116.htm.

[60] *See* 21 C.F.R. §§ 520.1192, 520.1194, 520.1195, 520.1198, 520.2044; see further detail included on Exhibit 1.

[61] http://www.anabolicsmall.com/equipoise.html.

[62] 21 C.F.R. § 522.204; see further detail included on Exhibit 1.

[63] 21 C.F.R. § 522.246; see further detail included on Exhibit 1.

serious health problems or even be fatal. Even a single exposure could cause irreversible mutations of human chromosomes.[64]

13. *Excede*, an antibiotic drug containing *ceftiofur cystalline free acid*, is "[n]ot for use in humans" and that if a person is exposed, that a physician should be consulted.[65]

14. *Chloramphenicol* is a topical antibiotic ointment. If ingested by humans, it can cause tragic consequences, including death and severe blood disorders.[66] In some forms, it is wholly prohibited for use on animals who become food.[67] In others, it is allowed without condition.[68]

15. *Kopertox* is used to treat thrush (a common bacterial infection of the hoof) in horses. Its active ingredient is *copper naphthenate* which, if eaten, may cause vomiting, shock, jaundice, and liver, kidney or central nervous system failures.[69] The law forbids the use of horses for meat, if they have been treated with *copper naphthenate*.[70]

16. *Cupric sulfate* is the active ingredient in *Proudsoff*, used to treat certain types of unwanted granulation tissue (proud flesh"). If eaten by humans, *cupric sulfate* can cause gastrointestinal tract problems including bleeding, liver damage, anemias, urinary system problems, and cardiovascular problems.[71]

17. *Farnam Repel* and other fly sprays used to control flies on horses contain *deodorized kerosene*. If any of that substance was in horse meat, the potential problems upon ingestion could include pulmonary edema, central nervous system depression, convulsions and loss of consciousness.[72]

18. *Deslorelin* is used in order to induce ovulation, as a regular tool for successful horse breeding. Federal regulations forbid its use in horses who will be eaten.[73] This is undoubtedly because the drug can cause serious

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[64] http://datasheets.scbt.com/sc-204668.pdf; see further detail included on Exhibit 1.

[65] http://animalhealth.pfizer.com/sites/pahweb/US/EN/Products/Documents/Combined%20Full%20PI%20(8_5x11)%20-%20EXEQ0110014.pdf. *See also* 21 C.F.R. §§ 522.313a, 522.313c (not to be used in horses who are eaten); see further detail included on Exhibit 1.

[66] http://www.drugs.com/cdi/chloramphenicol.html.

[67] 21 C.F.R. § 524.390 (Chloramphenicol ointment).

[68] See further detail included on Exhibit 1.

[69] http://www.sciencelab.com/msds.php?msdsId=9923553.

[70] 21 C.F.R. § 524.463; see further detail included on Exhibit 1.

[71] http://www.sciencelab.com/msds.php?msdsId=9923598; see further detail included on Exhibit 1.

[72] http://www.sciencestuff.com/msds/C1955.html; see further detail included on Exhibit 1.

[73] 21 C.F.R. § 522.533.

adverse reactions related to hormonal effects.[74]

19. *Dexium (dexamethasone)* injection and tablets are used as anti-inflammatory agents in horses, but are expressly banned from use in food animals because of the great danger from ingestion. *Dexium* is a steroid that is very hazardous if eaten.[75] Any use of it is banned by law for horses "intended for food."[76] *Methylparaben*, also in *Dexium* injections, is used as a preservative in cosmetic products, and its toxicity is established, but the exact scope and nature of the toxicity in humans is unknown.[77]

20. *Diclofenac sodium* (marketed as *Surpass*) is used for pain associated with arthritis in horses. While it is also used in human medicine, the drug is very dangerous, used only when necessary, and in the shortest duration possible. There are many known adverse reactions and side effects,[78] and the FDA prohibits its use in animals who become food.[79]

21. *Dormosedan*, the brand name for *detomidine hydrochloride*, is a common sedative and analgesic for many routine procedures performed on mature horses. No animal that has been administered this drug can legally be used for food.[80]

22. *Doxycycline*, an antibiotic also used in humans, has several severe side effects for humans who have sensitivities or compromised health that would indicate that they should not take the drug. The potential adverse effects include fetal injury, damage to tooth development in children, kidney problems, and bacterial resistance.[81]

23. Injectable *enrofloxacin* can cause significant problems if animals who have been treated with this antibiotic are eaten by humans. The Center for Veterinary Medicine specifically directed that the drug should be removed from use on chickens because chickens treated with the drug, who were then eaten by humans, passed on drug-resistant bacteria, a significant health hazard to humans.[82]

24. *Eucalyptus oil* is used as a topical treatment for horses (also known as "Scarlet Oil") for small wounds. Despite use in some compounds

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[74] *See, e.g.*, http://www.pdr.net/drugpages/concisemonograph.aspx?concise=2848; see further detail included on Exhibit 1.

[75] http://www.drugs.com/vet/dexium-injection.html.

[76] 21 C.F.R. § 522.540.

[77] http://www.sciencelab.com/msds.php?msdsId=9926083; see further detail included on Exhibit 1.

[78] http://www.pdr.net/search/searchResult.aspx?searchCriteria=Diclofenac+Sodium; see further detail included on Exhibit 1.

[79] 21 C.F.R. § 524.590.

[80] 21 C.F.R. §§ 522.536, 529.536; see further detail included on Exhibit 1.

[81] http://www.drugs.com/cdi/doxycycline-capsules.html; see further detail included on Exhibit 1.

[82] http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm042004.htm; see further detail included on Exhibit 1.

marketed to humans, eucalyptus is a known extreme human toxin if eaten.[83]

25. *Flunixin*, the active compound found in many equine pain medications, is a *non-steroidal anti-inflammatory drug*, or NSAID. NSAIDs cause severe and dangerous reactions in some humans. While many NSAIDs are used by people, the NSAIDs have significant potential adverse effects when combined with other drugs. There are also serious contraindications for use of NSAIDs in humans who have heart, liver, or kidney problems; who are taking other types of pain relievers, steroids or anticoagulants; and in third-trimester pregnancies. Several other NSAIDs are on the list as well, all of which could lead to the same problems,[84] and federal law has banned all of them in horses used for food.[85]

26. *Furaltadone*, a common antibacterial used in horses, is definitely "harmful if swallowed," has carcinogenic effects and, of even greater concern, the actual detrimental effects of the drug on humans who eat it has not been studied and is not known.[86] Other antibacterials also threaten human health if ingested, and are banned by law.[87]

27. *Furazolidone* is an antibacterial drug that is used in both horses and humans. Its use is carefully restricted in humans, however, because of the dangerous side effects from ingestion. For example, severe hypertension can result from the combination of furazolidone and certain food and drink, including alcoholic beverages.[88] It is also banned for use in horses who will be eaten.[89]

28. *Gentamicin sulfate* is used in humans and horses as an antibacterial. However, when prescribed for humans, doctors are careful to ensure that their patients are not taking other medications which can combine with gentamicin and cause severe kidney and hearing problems.[90] There are many other side effects of gentamicin ingestion that patients are warned

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[83] See further detail included on Exhibit 1.

[84] *See, e.g.*, http://www.drugs.com/vet/ketofen.html.

[85] *See, e.g.*. 21 C.F.R. § 522.1225; 21 C.F.R. §§ 520.930; 522.930 (*Equioxx*, containing the substance *firocoxib* – "Do not use in horses intended for human consumption"); 21 C.F.R. §§ 520.970; 522.970 (*Banamine*, *Flunazine*, and *Flunixamine* products, containing *Flunixin*); see further detail included on Exhibit 1.

[86] http://www.chemblink.com/MSDS/MSDSFiles/139-91-3_Sigma-Aldrich.pdf; see further detail included on Exhibit 1.

[87] *See, e.g.*, 21 C.F.R. § 520.2215 (*Sulfadiazene*, marketed as *Tribrissen 400*, an antibacterial oral paste, not to be used in horses intended for human consumption). *See also* 21 C.F.R. §§ 520.2611, 520.2613 (*Trimethoprim*, found in multiple products including both *Uniprim* antibiotic powder and *Tribrissen*, is banned by the FDA for use in food animals).

[88] http://msds.farnam.com/m000394.htm; see further detail included on Exhibit 1.

[89] 21 C.F.R. § 524.1005.

[90] http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682275.html; see further detail included on Exhibit 1.

about, including vomiting, fatigue, and muscle weakness, among others,[91] which is probably also why it has been banned for use in animals intended to be food.[92]

29. *Hyaluronate Sodium*, marketed as *Legend*, is used to treat an arthritic condition in horses. It is illegal to use this drug on horses who will be food.[93]

30. The use of *isoflurane*, a commonly used anesthetic gas for humans and horses, renders horses unfit for human consumption.[94] Federal law has barred other anesthetic compounds as well.[95] Studies have not addressed the effect of these drugs on the flesh of horses, and so the consequences for humans who eat those horses are completely unknown.

31. *Levothyroxine Sodium* (marketed as Thyro-L) is a thyroid-replacement hormone. The thyroid gland is a very sensitive, vital regulator of various bodily functions. Administration of even small amounts of thyroid replacement hormones can have detrimental effects on humans, including systemic toxicity, cardiovascular problems, aggravation of diabetes problems, and other hormonal effects.[96]

32. *Luprostiol*, a female hormone used in horses to manipulate estrus cycles and to chemically terminate pregnancies, cannot legally be used in food horses.[97] There is of course a potential for hormonal effects in women who eat horse meat from horses who have been given *luprostiol*.

33. *Methylandrostenediol* is an anabolic steroid used for a variety of reasons for sport horses, and by humans, often in the bodybuilding setting. The use in humans is highly controversial and the effects of exposure potentially detrimental to multiple body systems. Another drug in the same group, *Stanozolol*, is banned in food animals, by law.[98] Other steroids, perhaps even more dangerously, have no restrictions at all, are

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[91] http://www.drugs.com/pro/gentamicin-sulfate.html.

[92] 21 C.F.R. § 529.1044a.

[93] 21 C.F.R. § 522.1145. *See also* http://www.medi-vet.com/Polyglycan.aspx (Hyaluronic acid sodium salt for use "only in animals not intended for food use."); see further detail included on Exhibit 1.

[94] 21 C.F.R. § 520.186.

[95] *See, e.g.*, 21 C.F.R. § 522.1372 (*mepivicaine*).

[96] http://www.drugs.com/vet/thyro-l.html; see further detail included on Exhibit 1.

[97] 21 C.F.R. § 522.1290. The drug is so dangerous to humans that the FDA requires that the product include a label that says, among other things, that "[w]omen of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early states, women may be unaware of their pregnancies. Luprostiol is readily absorbed through the skin and can cause abortion and/or bronchiospasms." See further detail included on Exhibit 1.

[98] 21 C.F.R. § 522.2150.

used in horses, and can have severe detrimental effects on humans.[99]

34. *Methylprednisolone* and *prednisone* are used regularly in horses, while use in humans must be undertaken only with careful physician's supervision and with a prescription. The requirement for a physician's approval, coupled with the deleterious side effects, are likely what caused the federal government to ban the drugs for use in horses used for food.[100]

35. *Moxidectin* is used as a dewormer and marketed as *Quest*. And like most of the drugs on this list, its sellers must label the product as "[n]ot for horses or ponies intended for human consumption."[101]

36. *N-(2-Ethylhexyl)-5-norbornene-2,3-dicarboximide*, an active ingredient in "*Bug Block*" fly control, is "harmful if swallowed [and m]ay cause gastric distress, stomach pains, vomiting and diarrhea."[102]

37. *Neomycin sulfate* and many other antibiotic ointments are used on horses, just as they are on humans. But the strong caution with the use of such substances is that they should not be used unless there is an active infection – otherwise bacterial resistance and other serious side effects can occur.[103] Additionally, because they are ointments, they are not intended for oral ingestion.

38. *Omeprazole*, marketed as *Gastrogard*, is a commonly-used drug to aid in the protection and relief of stomach ulcers. Though also used in human drugs, its use in horses intended for food is expressly prohibited under federal regulations.[104]

39. *Phenylbutazone*, marketed as *Butazone*, *Bute* and *Butequine*, is barred by

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[99] *See, e.g.*, http://www.drugs.com/vet/uni-bol-can.html (*Uni-Bol*, containing *testosterone enanthate*, an anabolic steroid simulating a male hormone, used on horses with multiple adverse reactions in humans).

[100] 21 C.F.R. §§ 522.1410 (methylprednisolone), 522.1890 (prednisone); see further detail included on Exhibit 1.

[101] *See* 21 C.F.R. §§ 520.1452, 520.1463; see further detail included on Exhibit 1; *see also generally* FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods, (H.H.S. 2005), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/UCM113433.pdf (attached hereto as Exh. 19); 21 C.F.R. § 520.905a (common dewormer *Panacur* (*fenbendazole*) cannot be used on any horse who will be eaten). *See also* 21 C.F.R. § 520.1638 (*Oxibendazole*, active ingredient in the dewormer *Anthelcide EQ*).

[102] http://www.statelinetack.com/ContentFiles/Associated_Content/absorbinebugblockMSDS.pdf; see further detail included on Exhibit 1.

[103] *See, e.g.*, http://www.pdr.net/drugpages/concisemonograph.aspx?concise=3174; http://www.drugs.com/vet/equifur-can.html (Nitrofurantoin); http://www.drugs.com/vet/niderm-ointment-can.html (*Nitrofurazone*, an active ingredient in *Nitroderm* ointment, an antibacterial ointment that "[f]ederal law prohibits the administration of this preparation to animals that produce food or that are intended for consumption as food.").

[104] 21 C.F.R. § 520.1615; see further detail included on Exhibit 1.

law from use in horses who are eaten,[105] undoubtedly because of its significant adverse effects on humans.[106]

40. Horses are regularly treated with *insecticides* with known health risks for humans and others. For example, *Mosquito Halt*, containing the substance *Prallethrin*, can cause serious problems affecting multiple body systems.[107]

41. A series of drugs that affect thyroid function in horses, known as *thyrostats*, are used without significant control in America. However, the European Union has permanently banned the importation, purchase or sale of animals or meat of any animal that has been treated with these substances, because of their adverse characteristics.[108]

42. *Triamcinolone acetonide*, an ingredient in popular topical creams and liquids, is applied regularly to American horses in products such as *Animax*. It is specifically prohibited for use in horses who will become meat.[109]

43. Many other drugs used on horses for various medical treatments and problems are also directly banned by a series of federal regulations. Because of the FMIA's concern for public safety, and the FSIS' mandate to protect the public from animals or meat that have the potential for consumer harm, any horse who receives these prohibited drugs should be certified "USDA Condemned," and that horse's meat should be deemed adulterated by the FSIS. The meat of those horses should be excluded, permanently and as a matter of law, from the food supply.[110]

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[105] 21 C.F.R. §§ 520.1770a.

[106] *See, e.g.*, Nicholas Dodman, Nicolas Blondell, Ann M. Marini, "*Association of phenylbutazone usage with horses bought for slaughter: A public health risk*", FOOD AND CHEMICAL TOXICOLOGY 48 (2010) 1270–74, *available at* http://www.equinewelfarealliance.org/uploads/Food_and_Chemical_Toxicology_FINAL.pdf (attached hereto as Exh. 20) ("*Phenylbutazone Health Risks*"); U.S. Food & Drug Administration, "FDA Order Prohibits Extralabel Use of Phenylbutazone in Certain Dairy Cattle," *available at* http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm124078.htm (accessed Feb. 9, 2012) (attached hereto as Exh. 21) ("Phenylbutazone is known to induce blood dyscrasias, including aplastic anemia, leukopenia, agranulocytosis, thrombocytopenia and deaths . . . [and] is a carcinogen, as determined by the National Toxicology Program."); see further detail included on Exhibit 1.

[107] *See, e.g.*, http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35755; see further detail included on Exhibit 1.

[108] *See, e.g.*, Directive 2008/97/EC (2008) http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=EN&numdoc=32008L0097 (attached hereto as Exh. 22); see further detail included on Exhibit 1.

[109] 21 C.F.R. §§ 520.2483, 522.2483.

[110] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 8-11. *See also* 21 C.F.R. § 520.606 (Diclazuril, used for treatment of a form of myeloencephalitis); § 520.1855 (Ponazuril, marketed as Marquis, also used for myeloencephalitis treatment, with no information known on human toxicity); § 520.766 (Domperidone, used for toxicity in pregnant mares); 21 C.F.R. § 520.784 (Doxylamine succinate: used as an antihistamine substitute); 21 C.F.R. § 522.2063 (Pyralamine maleate).

44. Other drugs listed on Exhibit 1 are also used by humans, and may even be safe for a significant portion of the human population – but the dangers of ingestion to humans who may have allergies, sensitivities, and adverse reactions to those drugs, have also led to the absolute legal prohibition on use of those drugs in food animals.[111]

The list above represents only some examples of the substances listed on Exhibit 1, and Exhibit 1 is itself just a sampling of the drugs and substances that American horses are constantly treated with, fed, or injected with during their lives.[112] An accurate list cannot be compiled without an extensive review of every equine products catalogue, equine supply store and equine product website containing the various substances and drugs commonly used on horses in America – and that is without considering all the homemade remedies that are undoubtedly used on horses around the country. The illustrations here and on Exhibit 1 are telling, however, since they present a long list of substances which, if ingested, could cause a parade of problems and adverse reactions, illnesses and potential fatalities, if American horses continue to be slaughtered for food.[113]

E. Commercial Horse Slaughter Cannot Be Accomplished Without Horrendous Treatment of the Horses.

From their acquisition at livestock auctions and other sources to the slaughterhouse, horses destined for human consumption are subject to mistreatment and cruelty.[114] Their transportation from the livestock auction to the slaughter facility is often long and grueling, because they are cramped in trucks that do not accommodate their physical requirements and unique temperaments.[115] At slaughter facilities, horses are often subject to appalling abuse

[111] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 8-11. *See also* 21 C.F.R. §§ 524.660a, 524.660b (Dimethylsulfoxide solution and gel, regularly used for topical relief of swelling due to trauma).

[112] Exhibit 1; Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[113] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 8-11.

[114] *See* Larson Dec., Exh. 3, ¶¶ 12-13, 15-16, 18-19, 25.

[115] Larson Dec., Exh. 3, ¶¶ 12-13, 16, 25; *see* C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999) ("Horses tend to travel longer distances to slaughter than other livestock, because there is a limited number of equine slaughterhouses.") *available at* http://jas.fass.org/content/77/11/2925 (attached hereto as Exh. 23).

before and during their slaughter.[116] Some horses may even be slaughtered while still conscious.[117] Each aspect of this treatment increases the possibility that their meat is inappropriate for consumption under the FMIA and FSIS regulations discussed in Section V. below.[118]

Poor conditions during the transportation of horses result in slaughter facilities filled with frightened, food- and water-deprived, sick and injured horses.[119] Federal law usually requires transported horses to be off-loaded for food and water every twenty-eight hours, but horses are often transported continuously for over thirty hours.[120] Traveling in double-deck trailers meant for cows and pigs until late in 2011, some horses were unable to hold their heads in a natural position.[121] Some horses arrive at slaughterhouses with their backs broken or with other serious injuries.[122] And the lack of proper food and water in already weakened horses can lead to further injuries and death during extended transport. According to a 1999 study of sixty horses transported for slaughter, one animal had to be removed from the transport trailer after twelve hours of transport, dying two days later.[123] The fifty-nine arriving horses sustained a total of eighty-one injuries.[124]

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[116] *See* Larson Dec., Exh. 3, ¶¶ 15, 18-19.

[117] *Id*. at ¶ 18.

[118] *Id*. at ¶¶ 14, 16.

[119] *Id*. at ¶¶ 16, 18.

[120] T.H. Friend, *A Review of Recent Research on the Transportation of Horses*, J. ANIM. SCI. 79:E32-E40 (2001) ("Continuous transport of slaughter horses for 30 hours is common, and some trips last 36 hours or longer.") *available at* http://jas.fass.org/content/79/E-Suppl/E32 (attached hereto as Exh. 24).

[121] Larson Dec., Exh. 3, ¶ 13. In September 2011, the USDA announced a new rule which closed a loophole that allowed double-decker transport to continue for horses being driven to slaughter. 76 Fed. Reg. 55213. A bill is currently pending in Congress that would make that rule a matter of statutory law.

[122] *See* Larson Dec., Exh. 3, ¶ 13; *see also* 151 CONG. REC. H4247 (horses are "transported in excess of 1,000 miles in the most inhumane conditions perceived").

[123] C.L. Stull, *Response of Horses to Trailer Design, Duration, and Floor Area During Commercial Transportation to Slaughter*, J. ANIM. SCI. 77:2925-2933 (1999), *supra* Note 115.

[124] *Id*.

The arduous trip to slaughter facilities is frightening for most horses but is especially traumatic for wild horses, who resist handling during gather and transport operations.[125] Because of their wildness, the fear they display in response to proximity to people in strange environments, and their resistance to handling and transport, wild horses experience extremely high levels of distress and injury during the events leading up to slaughter.[126]

The mistreatment continues at the end of the transport phase. Many horses are not given hay or water in overnight holding pens.[127] Many of the horses in holding pens are "downers" – animals too sick or injured to stand up and walk, some of whom may be dragged or pushed into the pen.[128] Some of these ill, diseased, and injured animals are unfit for food under the FMIA and should not be slaughtered for human consumption.[129]

Because they frighten more easily than cows, horses are unsuited to be processed at a slaughter plant.[130] As horses are more sensitive to odors than cows, the scent of blood that necessarily exists in the slaughter facility exacerbates their fright.[131] Some horses slip and fall in

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[125] Larson Dec., Exh. 3, ¶ 25.

[126] *Id*.

[127] *See Pasture to Plate: A Report by the Canadian Horse Defence Coalition on Equine Slaughter*, p. 5 (July 2011), *available at* http://canadianhorsedefencecoalition.files.wordpress.com/2011/12/pasture-to-plate.pdf ("*Pasture to Plate*") (attached hereto as Exh. 25).

[128] Larson Dec., Exh. 3, ¶ 14; *see also* Gary D. Anderson & Don R. Lee, *Salmonella in Horses: A Source of Contamination of Horse Meat in a Packing Plant Under Federal Inspection*, 31 Applied and Environmental Microbiology 661 (1975) ("[S]laughter horses have usually been trucked for extensive distances. Many times they are injured or unhealthy, housed poorly, fed and watered improperly, and sometimes held for long times, as much as a week, in dirty confined pens at the slaughter plant.") *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC291172/ (attached hereto as Exh. 26).

[129] *See* 21 U.S.C. § 601(m)(3), (4) (defining "adulterated" to include animals or meat that are (a) "for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food," or (b) "held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health"). The FMIA is discussed in detail in Section V.A., *infra*.

[130] *See* Larson Dec., Exh. 3, ¶¶ 18, 25.

[131] *See* Larson Dec., Exh. 3, ¶ 18.

the stun box.[132] As a result of their keen perception and subsequent fear, horses are more likely to injure themselves trying to escape the slaughter plant.[133]

Under federal law, horses must be rendered unconscious prior to slaughter,[134] but because of their natural agility and flight instinct, many horses are improperly stunned and remain conscious when they are hoisted to have their throats cut.[135] According to a recent report, almost half of the horses going to slaughter had to be stunned more than once.[136] The desire to slaughter as many horses as quickly as possible inevitably contributes to the inaccuracy and cruelty of the slaughtering process.

FSIS and USDA are aware of and have documented appalling cruelty at slaughter plants, including gruesome descriptions and photographs of the mistreatment inherent in horse slaughter.[137] The mistreatment seems to be an inevitable occurrence anytime that horses are slaughtered, as documented most recently in Canada.[138] The examples cited in this section, which are only those that were discovered and occurred in a small sampling of plants, speak

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[132] *See id*. at 4.

[133] *See id*. at 5.

[134] *See* Humane Methods of Slaughter Act, 7 U.S.C. § 1902(a).

[135] *See* 151 CONG. REC. S10,220 (daily ed. June 8, 2005) ("horses sometimes remain conscious throughout the slaughter process"). *See also* Larson Dec., ¶ 18.

[136] *Pasture to Plate, supra* Note 127, at 4.

[137] *See, e.g.*, USDA, Food Safety & Inspection Service, Noncompliance Record No. 0019-2005-8243 (Apr. 13, 2005) (attached hereto as Exh. 27); *see also, e.g.*, Noncompliance Record Nos. 00 18-2005-8243 (Apr. 4, 2005) (attached hereto as Exh. 28) ("Nine horses were overcrowded in the alleyway causing undue excitement which was further exacerbated when two more employees from the kill floor began yelling and hitting these horses causing the one in the end of the line to slip and fall."); 0013-2006-8243 (Oct. 9, 2006) (attached hereto as Exh. 29) ("horse was down" . . . "in the upper middle compartment of a pot bellied trailer" and "[o]ther horses within the compartment were trampling the downed horse"); 0006-2007-8243 (Jan. 24, 2007) (attached hereto as Exh. 30) ("two downed horses being trampled upon by the other horses as well as the front horse being kicked with the hind feet from another horse"); Press Release, Animals' Angels (Nov. 2008), *available at* http://www.kaufmanzoning.net/nov24/pressrelease.pdf (attached hereto as Exh. 31); *see also* Mary Nash's Horse Meat Website, *available at* http://www.kaufmanzoning.net/foia.htm (attached hereto as Exh. 32) (making available for download USDA documents describing and depicting regulatory violations, mistreatment, and cruelty).

[138] *See generally Pasture to Plate, supra* Note 127.

volumes for the absolute terror that slaughterhouses are for horses, and the danger to them and to the public in processing them for meat.

F. Horse Slaughter Leads to Other Public Health Problems.

Not only does horse slaughter pose danger to those who consume horse meat, and inflict cruelty upon the horses, but horse slaughter facilities – to a greater degree than other slaughterhouses – also harm the environment, overwhelm local governments, diminish quality of life, and threaten public health. There has been a growing and "overwhelming public sentiment that horse slaughter for human consumption should be ended,"[139] and to prohibit activities which "have detrimental impacts on the health, safety, environment, and welfare of" humans living in proximity to horse slaughter plants.[140] These problems are exacerbated by nonresident owners of slaughterhouses who have no reason or motivation to be concerned about the community in which their facilities are located. For example, the company that owned the last of the Texas horse slaughter facilities demonstrated "extreme disregard" towards the local citizenry and government.[141]

Every one of the last three American horse slaughterhouses[142] wreaked environmental havoc by dumping blood, entrails, urine, feces, heads, and hooves into local systems, overwhelming waste water infrastructures and leading to numerous environmental violations.[143]

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[139] Ltr. From Hon. Robert S. Molaro (June 11, 2007) ¶ 3, in support of Illinois law banning slaughtering of horses for human consumption, 225 ILCS § 635 ("*Molaro Letter*"). *See also ASPCA Survey*, *supra* Note 22.

[140] *Molaro Letter*, *supra* Note 139, ¶ 5.

[141] Jane Allin, *When Horse Slaughter Comes to Town*, p. 3 (Mar. 2011), *available at* http://www.horsefund.org/resources/When_Horse_Slaughter_Comes_to_Town_Updated_March_2011.pdf ("*When Slaughter Comes to Town*") (attached hereto as Exh. 33); *Life In A Slaughter Town: Kaufman, Texas*, pp. 4, 10, *available at* http://galleries.forbes.com/gallery/Life_in_a_Slaughter_Town%3A_Kaufman,_Texas#image=03PB6Ww0dV53u&view=filmstrip ("*Life In A Slaughter Town*") (attached hereto as Exh. 34).

[142] The last three horse slaughterhouses in America, which closed in 2007, were in DeKalb, Illinois (Cavel), Kaufman, Texas (Dallas Crown), and Fort Worth, Texas (Beltex).

[143] *See When Slaughter Comes to Town*, *supra* Note 141, at 3. *See also* Eckhoff, Vickery, "Horse Slaughterhouse Investigation Sounds Food Safety and Cruelty Alarms," *Forbes*, Dec. 6, 2011, available at http://www.forbes.com/sites/vickeryeckhoff/2011/12/06/horse-slaughterhouse-investigation-sounds-food-safety-and-cruelty-alarms/ (accessed Jan. 15, 2012) ("*Slaughterhouse Food Safety & Cruelty*") (attached hereto as Exh. 35).

According to the former mayor of Kaufman, Texas, where the Dallas Crown plant was located, the problems were epidemic, including (1) a pervasive and horrible odor in the vicinity of the plant; (2) multiple violations of the plant's industrial waste permit; (3) denial of access to city inspectors for waste water testing; (4) transportation of slaughter refuse in leaking containers without covers, leading to horse parts falling into the road; (5) blood flowing in nearby ditches; and (6) bones and blood in front of the facility and in neighboring yards, attracting dogs and other animals.[144] Dallas Crown also left a 600-gallon container filled with blood and horse parts outside its facility, generating a stench and attracting flies and vermin.[145] In 2003, the container spilled outside the plant, emptying blood into a ditch, and, from there, into the ground.[146]

The frequency and magnitude of Dallas Crown's environmental damage and legal breaches devastated the community. The cost of enforcing all violations for which Dallas Crown was cited would have consumed the city's entire legal budget for the year, and the company simply ran the legal expenses up so that the city was unable to adequately respond.[147] This included the costs of the twenty-nine individual jury trials requested by Dallas Crown for its waste water violations, each of which resulted in a $2,000 fine.[148]

Due to its lack of funds, Kaufman was unable to prosecute and collect on those fines.[149] Even so, the city spent over twice as much on legal fees related to Dallas Crown's violations as the company paid in property taxes.[150] Overall, the horse slaughter business nearly destroyed the

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[144] Former Mayor Paula Bacon, Open Letter to State Legislatures Considering Pro-Horse Slaughter Resolutions (Feb. 2009), *available at* http://www.animallawcoalition.com/horse-slaughter/article/686 ("Paula Bacon Letter") (attached hereto as Exh. 36); *see also* Eckhoff, Vickery, "Texas Mayor Paula Bacon Kicks Some Horse Slaughter Tail," *Forbes*, Jan. 10, 2012, *available at* www.forbes.com/sites/vickeryeckhoff/2012/01/10/texas-mayor-paula-bacon-kicks-some-tail/ (accessed Jan. 15, 2012) (attached hereto as Exh. 37).

[145] *Life In A Slaughter Town*, *supra* Note 141, at 9.

[146] *See id.*

[147] Paula Bacon Letter, *supra* Note 144.

[148] *Id*.

[149] *Id*.

[150] *Id*.

town – breaking laws, paying virtually no taxes, forcing the city to use valuable resources to protect the environment, and overwhelming the city's water system.[151]

In addition to endangering the ultimate consumer of the meat, horse slaughter facilities also diminish the quality of life and threaten public health. The omnipresent putrid air of the slaughterhouse dampens communities, drives citizens away, and depresses real estate values.[152] In Kaufman, Texas, the ultimate insult came when, on multiple occasions, residents' faucets delivered blood and horse tissue instead of water.[153] Most notably here, even the Sanitation Group of DeKalb, Illinois described the discharge from the Cavel facility as "uniquely acute," given that horses are given a "wide range of drugs" that are "clearly labeled NOT FOR USE IN HORSES INTENDED FOR HUMAN CONSUMPTION."[154] Horse blood disposal presents a similar and related problem: with horses having twice as much blood as cows, the bacterial agents used to neutralize cows' blood are insufficient to treat horse blood due to the antibiotics in it.[155] Moreover, the byproducts of horse slaughter – especially blood, sludge, and waste water – may contaminate groundwater used for consumption and even enter the food chain when sludge is distributed on crops.[156] Consequently, even individuals who choose not to eat horse meat may unintentionally be exposed to the drugs, treatments and substances listed on Exhibit 1 – all potentially harmful and all possibly entering the food and the water supply.[157]

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[151] *When Slaughter Comes to Town*, *supra* Note 141, at 5 ("It is entirely foreign owned, and pays no corporate taxes or export tariffs. The horse slaughter industry is economically insignificant.").

[152] *See, e.g.*, *Life In A Slaughter Town, supra* Note 141, at 5, 10, 13.

[153] *When Slaughter Comes to Town*, *supra* Note 141, at 3.

[154] *Id.* at 4 (emphasis in original).

[155] *Id.*

[156] *Id.*

[157] *See generally* Section V.C, *infra*.

V. LEGAL BACKGROUND

A. Federal Regulation of Horses Slaughtered for Human Consumption Under the Federal Meat Inspection Act, 21 U.S.C. §§ 601, *et seq.*

Congress enacted the Federal Meat Inspection Act ("FMIA") in 1907 in order to protect the food supply and ensure people do not experience any untoward effects from eating meat.[158] The FMIA prohibits the sale, receipt, and transport of "adulterated" carcasses and meat.[159] Several factors that render meat legally adulterated are prevalent in American horses, and as a consequence of horse slaughter practices, as explained in detail here and in Section VI.A. below.[160]

The Secretary of Agriculture has delegated to the FSIS the authority to exercise USDA's functions under the FMIA.[161] The FSIS primarily fulfills those duties by performing mandatory inspections of all animals processed at U.S. slaughterhouses, before and after slaughter, to ensure that no adulterated meat enters the human food supply.[162] Meat that does not pass inspection cannot be sold, received or transported.[163] If horse slaughter begins again in America, each horse presented for slaughter will need to be screened for exposure to the many banned and dangerous substances listed in Exhibit 1, as well as other drugs and conditions that could render them adulterated under the FMIA.[164]

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[158] 21 U.S.C. § 602.

[159] *Id*. § 610(c).

[160] *Id*. § 603(m)(1),(2)(A),(C),(3).

[161] 9 C.F.R. § 300.2. Pursuant to this delegation, the FSIS Administrator may take any action, authorize any expenditure, and promulgate any rule, regulation, or order that is lawful under the FMIA, Humane Slaughter Act, 7 U.S.C. §§ 1901-1906, and related statutes. *See* 7 C.F.R. §§ 2.18, 2.53.

[162] 9 C.F.R. § 302.1 (mandating inspection, with a few exceptions, of every establishment "in which livestock are slaughtered for transportation or sale as articles of commerce . . ."); 21 U.S.C. § 603 (mandating ante-mortem examination and inspection of animals intended for use as food); 21 U.S.C. § 604 (mandating post-mortem examination and inspection of animals intended for use as food).

[163] 21 U.S.C. § 610(c)(2).

[164] *Id.* § 601(j) (defining "meat food product" to include equines).

1. Meat from Horses Administered Certain Drugs or That Contains Certain Food Additives or Drug Residues Is Adulterated and Cannot Be Sold Legally.

Under the FMIA, "adulterated" meats are unsafe and cannot be sold to the public.[165] The FSIS establishes, and enforces, standards for determining whether meat is adulterated.[166] For purposes of the Petition's requests, horse meat is adulterated under the FMIA if it (1) contains any added substance that may render it "injurious to health,"[167] (2) has any added substance that may make it "unfit for human food,"[168] or (3) it is "otherwise unfit for food."[169]

These definitions apply directly to horse meat and the requests in this Petition. Under the FMIA definitions just stated and FSIS regulations, horse meat will be adulterated if (1) it comes from a horse who was directly administered any of the products on Exhibit 1 that are prohibited for use in horses who will become food, unfit for use in horses, and illegal for use in horses;[170] (2) it bears or contains any food additive declared unsafe by the FDA;[171] (3) it contains a veterinary drug residue in an amount that exceeds FDA tolerance levels;[172] or (4) it is from a

[165] *Id*. § 610(c).

[166] 9 C.F.R. § 300.2; 7 C.F.R. § 2.7, 2.18, and 2.53.

[167] 21 U.S.C. § 601(m)(1) (Meat is adulterated "if it bears or contains any [added] poisonous or deleterious substance which may render it injurious to health. . . .").

[168] *Id*. § 601(m)(2)(A) (Meat is adulterated "if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food. . . .").

[169] *Id*. § 601(m)(3) (meat is adulterated if it is "for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food. . . .").

[170] *See* 21 C.F.R. §§ 520, 522, 524, 526, 529 (prohibiting the use of dozens of "new animal drugs" in animals intended for human consumption); 21 U.S.C. § 601(m)(2)(A) (establishing that meat is adulterated if "unfit for human food"), (m)(3) (establishing that meat is adulterated if "otherwise unfit for human food"); *see also* FSIS Notice 14-11, Inspection Responsibilities When a Chemical Residue Does Not Have an Established Tolerance (USDA 2011) (attached hereto as Exh. 38) (requiring that an entire carcass must be condemned if a muscle tissue residue sample tests positive for a substance for which there is no established tolerance).

[171] 21 U.S.C. § 601(m)(2)(C); *id*. § 348(a)(2); *see also* FDA Food Additive Status List, (H.H.S. 2012), *available at* http://www.fda.gov/food/foodingredientspackaging/foodadditives/foodadditivelistings/ucm091048.htm (listing all FDA food additives and their status) (attached hereto as Exh. 39).

[172] 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA); 21 C.F.R. §§ 520, 522, 524, 526, 529 (establishing drug residue tolerance levels); *see also* FSIS Notice 14-11, *supra* Note 170.

horse who was administered a substance, including those listed in Exhibit 1, that renders it "injurious to health" and unsafe for human consumption.[173]

The FSIS' findings regarding adulterated meat rely, in large part, on the FDA's determinations about the safety of certain drugs and chemicals.[174] One highly relevant group, identified throughout the Petition and in greater detail in Exhibit 1, is those substances which under federal law absolutely *cannot legally be administered* to food animals in any amount.[175] If an animal has been given any of those identified products, at any time, that animal cannot be turned into meat.[176] Any meat from such animals cannot be legally sold, is unfit for human food, and *must* be condemned.

Another relevant group of products is "food additives." Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), a "food additive" is, broadly, any substance that is intended for use in the production or manufacture of a food like horse meat, unless the substance is already generally recognized as safe, or is one of the substances enumerated in 21 U.S.C. § 321(s), including a "new animal drug."[177] Meat that contains an additive is presumed unsafe and its sale

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[173] *See* 21 U.S.C. § 601(m)(1) ("injurious to health"); 21 C.F.R. §§ 520, 522, 524, 526, 529 (prohibiting the use of dozens of "new animal drugs" in animals intended for human consumption); FSIS Notice 14-11, *supra* Note 170 (requiring condemnation of meat from horses in whom substances in 21 C.F.R. §§ 520, 522, 524, 526, and 529 are present in *any* amount); Exhibit 1.

[174] *See, e.g.*, United States National Residue Program, 2011 Scheduled Sampling Plans, p. vi (USDA 2011) (attached hereto as Exh. 40) (explaining that the FSIS relies on tolerances established by the FDA); 21 U.S.C. § 601(m)(2)(C) (adopting the FDA standard for unsafe food additives); 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA).

[175] *See* C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529.

[176] FSIS Notice 14-11, *supra* Note 170. One example of the many drugs in this category is phenylbutazone, which has five separate sections of the C.F.R. identifying different forms of the drug that are completely barred from any use in animals who become food. *See* 21 C.F.R. § 520.1720a (tablets and boluses of phenylbutazone cannot be used "in horses intended for human consumption"); *id*. § 520.1720b (granules: "Treated animals should not be slaughtered for food use."); *id*. § 520.1720c (paste: "Do not use in horses intended for human consumption."); *id*. § 520.1720d (gel: not for animals used as food); *id*. § 520.1720e (powder: cannot be used on horses used for human consumption).

[177] 21 U.S.C. § 321(s) (defining food "additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing [or] manufacturing . . .), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety,

(Footnote continued on next page)

is prohibited *unless* the FDA has expressly approved all additives that may be in it.[178] If a food such as horse meat contains an additive, the FDCA and FMIA automatically deem it adulterated and unsafe unless there is in effect a regulation prescribing the conditions under which the additive may be safely used and the additive is used in conformity with the regulation.[179]

A third class of products that may render meat adulterated are those drug residues which under FSIS regulations absolutely cannot be *present* in food animals or their meat in any amount.[180] Many of the substances in Exhibit 1 also fit in this category.[181] If a horse tests positive for any of those identified drug residues, that horse cannot be turned into meat.[182] And under FSIS rules, that meat *must* be condemned.[183]

(Footnoted continued from previous page)

as having been adequately shown through scientific procedures to be safe under the conditions of its intended use").

Contrary to the facial meaning of "generally recognized as safe and effective" ("GRASE"), drugs do not easily qualify as GRASE, which requires a finding by experts based on substantial evidence – evidence of adequate and well-controlled investigations by qualified experts backed by substantial support in scientific literature – plus a determination by the fact-finder that there is a general recognition of safety and effectiveness among the qualified experts. *See, e.g., United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219, 1229-30 (D. Minn. 1991), *aff'd*, 968 F.2d 681 (8th Cir. 1992). All drugs approved by the FDA for some use but that fail to qualify as GRASE are "new animal drugs." *See id.* at 1230. New animal drugs are subject to the FDA's premarketing clearance process. *See id.* New animal drugs can only be marketed for purposes expressly approved by the FDA. *See* 21 U.S.C. § 360b(a)(1)(A)-(C).

[178] *See id.* § 342(a) (food additives). All drugs approved by the FDA for some use but that fail to qualify as GRASE are "new animal drugs." *See Pro-Ag, Inc.*, 796 F. Supp. at 1230. New animal drugs are subject to the FDA's premarketing clearance process. *See id.* New animal drugs can only be marketed for purposes expressly approved by the FDA. *See* 21 U.S.C. § 360b(a)(1)(A)-(C).

[179] *Id.* § 348(a)(2).

[180] 9 C.F.R. § 318.20.

[181] *See* Exhibit 1.

[182] *See* 9 C.F.R. § 318.20; C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529.

[183] FSIS Notice 14-11, *supra* Note 170; 9 C.F.R. § 318.20; *id.* § 603(m)(1), (2)(A), (2)(C), (3); *id.* § 603(c).

A final relevant group of products is those, identified throughout the Petition, which render meat unsafe for human consumption or "injurious to health."[184] Many of the drugs and substances on Exhibit 1 qualify, as set out in the descriptions of the drugs in Exhibit 1. If an animal has ever been given any of those identified products, that animal cannot be turned into meat.[185] And under the FMIA, that meat *must* be condemned.[186]

2. The FSIS Screens Food Animals for Disease and Exposure to Dangerous Substances.

The FSIS, along with the FDA, is responsible for inspecting animals and their flesh to protect consumers from harmful residues.[187] Specifically, the FSIS conducts its investigations of potentially harmful residues, including food additives and veterinary drugs,[188] in animals who will be used for food, to help the FDA determine the parties responsible for violations and for introducing adulterated food into interstate commerce.[189] When conducting ante-mortem inspections and examinations, FSIS inspectors observe the animals at rest and in motion, focusing on their overall condition, their behavior, and the existence of any swelling or external abnormalities.[190] If an animal does not show signs of disease or abnormality and appears fit for

[184] *See* 21 U.S.C. § 601(m)(1) ("injurious to health"); C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529 (listing tolerances for dozens of veterinary drugs, including those banned from use in "horses intended for human consumption"); Exhibit 1.

[185] *See* 21 U.S.C. § 601(m)(1) ("injurious to health"); C.F.R., Title 21 ("Food and Drugs"), Parts 520, 522, 524, 526, and 529 (listing tolerances for dozens of veterinary drugs, including those banned from use in "horses intended for human consumption"); Exhibit 1.

[186] *See* 21 U.S.C. § 601(m)(1); *id.* § 610(c)(2).

[187] FDA Directive 7371.006, *supra* Note 101 (explaining that the FSIS is responsible for initial inspections and then reports drug residue violations to the FDA to follow up). FSIS jurisdiction over the safety of all meat sold to the public extends not only to meat but also to live animals who will become meat. 21 U.S.C. § 603 (granting jurisdiction over food animals); *id*. § 604 (granting jurisdiction over flesh of food animals).

[188] All "new animal drugs" are "veterinary drugs."

[189] FDA Directive 7371.006, *supra* Note 101, at 6. The FSIS also obtains names of producers and other parties involved in the sale of the animal at issue, informs producers of violations, and maintains Residue Repeat Violator Lists. Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, p. 68 (USDA 2011). (attached hereto as Exh. 41); United States National Residue Program, *supra* Note 174, at vi.

[190] FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, p. 4 (USDA 2009) (attached hereto as Exh. 42).

slaughter, the animal can be slaughtered.[191] And when conducting post-mortem inspections and examinations, FSIS inspectors inspect and observe the carcasses' physical condition, looking for (among other things) inflammation or swelling, pathology in the lymph nodes, cysts, and parasites,[192] and examine various organs and body parts.[193]

To ensure that slaughter establishments control harmful drug residues and keep the food supply safe, the FSIS executes the National Residue Program (the "NRP").[194] Under the NRP, the FSIS is responsible for collecting tissue samples at the ante- and post-mortem inspection stages to screen for contamination, comparing the amounts of detected substances to tolerances (if any exist) established by the FDA and EPA, and preventing adulterated meat from entering the food supply.[195] The FSIS engages in two types of testing – (1) "Scheduled Sampling," in which inspectors apply statistical sampling methods and randomly collect tissue samples from a pre-designated number of different types of animals who have passed ante-mortem inspection,[196] and (2) "Inspector Generated Sampling," in which inspectors collect tissue samples when they have reason to believe that a violative residue is present.[197]

Each calendar year, various federal agencies, including the FSIS, FDA, and EPA, create the Scheduled Sampling Plan,[198] deciding "which chemical compounds are tested in which food animals" and weighing practical considerations such as FSIS laboratory capacity and analytical

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[191] *Id*. at 5.

[192] FSIS Directive 6100.2, Post-Mortem Livestock Inspection, p. 6 (USDA 2007) (attached hereto as Exh. 43) (describing post-mortem inspection of cattle).

[193] *Id*. at 7.

[194] FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program, p. 2 (USDA 2007) (attached hereto as Exh. 44); United States National Residue Program, *supra* Note 174, at vii.

[195] Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, at 67.

[196] *Id.* at 69; FSIS Notice 40-11, Instructions for Carcass Selection for the National Residue Program Scheduled Samples (attached hereto as Exh. 45).

[197] FSIS Directive 10,800.1, *supra* Note 194, at 10; FSIS Notice 40-11, *supra* Note 196. A "violative residue" is residue from a substance in excess of the permitted amount under the FMIA, FDCA, or related FSIS or FDA regulations.

[198] The FSIS publishes finalized Scheduled Sampling Plans each year in the "Blue Book."

methods.[199] The agencies devise the plan based on samples from the NRP, information accumulated during previous investigations, and veterinary inventories completed during on-farm visits.[200] The agencies determine which chemical compounds put the human food supply at risk, use algorithms to rank the compounds, pair the compounds with appropriate products derived from food animals, and establish the number of samples to collect.[201] Because statistical evidence of violation rates is not available for many potentially tested compounds, the FSIS must estimate the overall violation rates for these compounds.[202] The program is inexact, even for its most controlled subjects. Many dangerous substances are not tested for at all. In 2006 and 2007, when horses were slaughtered for human consumption and tested under the Scheduled Sampling Plan, horses were only tested for *11 of the 115* commonly administered drugs listed in Exhibit 1.[203]

The Inspector Generated Sampling Program complements the Scheduled Sampling Program, requiring inspectors to collect tissue samples every time there is reason to believe that a violative residue is present.[204] If a concern arises about a violative residue, the FSIS conducts rapid, in-plant screening tests of the suspicious tissue.[205] This review is limited to triggers such as evidence of acute disease, questionable production practices, known herd history, relevant

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[199] United States National Residue Program, *supra* Note 174, at vi, 25.

[200] *Id*. at vi.

[201] *Id*. at 1.

[202] *Id*. at 21.

[203] *See* 2006 FSIS National Residue Program Data (USDA 2007) (attached hereto as Exh. 46); 2007 FSIS National Residue Program Data (USDA 2008) (attached hereto as Exh. 47); Exhibit 1.

[204] *See* FSIS Directive 10,800.1 *supra* Note 194, at 11 ("There are no exceptions to this direction. Inspection program personnel are to take a sample of any tissue that they believe may contain a violative level of chemical residue.").

[205] FSIS Directive 10,800.1, *supra* Note 194, at 11. Inspectors administer the Fast Antimicrobial Screen Test ("FAST") when they suspect illegal levels of antimicrobial drug residues and the Kidney Inhibition Screen (KIS™ Test) when they suspect illegal levels of antibiotics. Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, at 69-70. The FAST and KIS™ Test are "used to more closely monitor producers and others who are known historically to have marketed animals with violative concentrations of antimicrobial residues." *Id*.

environmental exposure, and threats to homeland security.[206] Further, FSIS inspectors must collect and test tissue from all animals identified as "U.S. Suspect" during ante-mortem inspection.[207]

If an in-plant screening is positive, the inspector sends the liver, kidney, and muscle tissues to an FSIS laboratory for further analysis.[208] If the in-plant screening is negative, the inspector must determine whether there is a reason to suspect that a violative residue other than an antimicrobial drug residue is present in the tissue.[209] Notably, the in-plant screen tests do not detect non-steroidal anti-inflammatory drugs, many of which can never be given to food animals.[210] Accordingly, only if inspectors suspect the use of these drugs, must they take tissue samples and retain the carcasses until receiving laboratory testing results.[211] If an animal's tissue tests positive for violative residues, the inspectors must condemn the carcass and all parts from an animal whose muscle tissue or fat contains a residue violation.[212] Moreover, FSIS inspectors must condemn the entire carcass if a sample collected and analyzed under the NRP is positive and "there is no FDA or EPA established tolerance for the identified residue in muscle,"[213] which describes over fifty of the drugs listed on Exhibit 1.

The slaughter establishments themselves are also responsible for ensuring the safety of the food supply. Every slaughterhouse must conduct a hazard analysis to determine the food

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[206] FSIS Directive 10,220.3, Using the Fast Antimicrobial Screen Test (FAST) to Detect Antimicrobial Drug Residues in Cattle and Swine, p. 2 (attached hereto as Exh. 48). Additional indicia of the need to test include mastitis, metritis, peritonitis, surgery, injection sites, pneumonia, pleuritis, pericarditis, endocarditis, septicemia, pyemia, or generalized disease, injury or inflammatory conditions, acute cellulitis or other acute inflammations, beta-agonist, signs of treatment. *Id*. at 3-4.

[207] *Id*. at 2.

[208] FSIS Directive 10,800.1, *supra* Note 194, at 11.

[209] *Id*.

[210] *See, e.g.*, FSIS Directive 10,800.1, *supra* Note 194, at 11; Exhibit 1 (Firocoxib, Flunixin, Ketoprofen, Phenylbutazone).

[211] FSIS Directive 10,220.3, *supra* Note 206, at 4.

[212] FSIS Directive 10,800.1, *supra* Note 194, at 17.

[213] FSIS Notice 14-11, *supra* Note 170.

safety hazards reasonably likely to occur in the production process and identify measures to prevent those hazards from occurring.[214] Examples of food safety hazards include the presence of drug residues and unapproved food additives in food animals and their meat.[215] After conducting a hazard analysis, each establishment must produce a Hazard Analysis and Critical Control Points ("HACCP") plan that lists food safety hazards which it must prevent or minimize and the processes or steps it can take to control each hazard.[216] The facilities are responsible not only for food safety hazards they introduce to the production process but also those introduced outside the establishment, including those that occur before entry into the establishment.[217] Failure to develop and implement an HACCP plan may render meat products produced by an establishment adulterated.[218]

3. Agency Reports Describe FSIS Screening of Animals and Flesh for Banned Substances as Inadequate.

In multiple respects directly relevant to the Petition and horse slaughter issues, current NRP sampling is inadequate. The scheduling algorithm is based on a "one size fits all" strategy and has not been updated for almost a decade.[219] And although the NRP is "resource intensive," it provides the FSIS with minimal information on the "true chemical residue burden" in inspected meat.[220] Further, the NRP is "slow to respond to emerging residue issues."[221] In sum, according to the USDA's own report on the primary residue inspection program for which FSIS is responsible, the sampling regime that American consumers rely on to keep unsafe drug residues and food additives out of their meat is both expensive and ineffective, yields insufficient

[214] 9 C.F.R. § 417.2(a)(1).

[215] *Id*. § 417.2(a)(3)(v), (ix).

[216] *Id*. § 417.2(c).

[217] *Id*.

[218] *Id*. § 417.2(e).

[219] Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, at 71.

[220] *Id.*

[221] *Id*.

information on risks to meat in the nation's food supply, and has not been updated in response to evolving threats.[222]

FDA investigations based on FSIS reports of tissue residue violations are also inadequate. The FSIS reports tissue residue violations to the FDA on a "single-animal basis,"[223] providing very limited information on a very limited number of animals. Because FSIS analysis of tissue samples may be restricted to the identification of only a single drug, food animals that (1) contain violative residues of multiple drugs (like horses often will), (2) have been exposed to hundreds of drugs, such as those listed in Exhibit 1, that are either banned completely and/or that are not tested for by FSIS at all, and (3) are tested by the FSIS, may not be reported to the FDA to pursue enforcement measures.[224] Put differently, meat from an animal that contains residue of a dangerous violative drug and is tested by the FSIS for a tissue residue violation is unlikely to be discovered under the "single-drug" testing, which means there may never be an FDA investigation or enforcement action against the producer.[225]

If the FSIS is aware of a first-time violation that does not evidence the presence of particularly dangerous drugs, the intentional misuse of a drug, or a complete disregard for withdrawal periods, "*resource constraints do not allow for an FDA investigation*."[226] In other words, there are an endless number of situations – known and unknown – where animals will be contaminated with toxic drugs, the FSIS will have knowledge of the contamination, and the FDA will have no ability to evaluate the dangers for consumers.[227] There are certainly an equally

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[222] *See id.*

[223] FDA Directive 7371.006, *supra* Note 101, at 18 (H.H.S. 2005).

[224] *See id.*

[225] The assurance of health threats under this testing regime is apparent with respect to horses based on the facts presented in the Petition, because every horse is given a long list of substances, on a regular basis, that are absolutely prohibited, not tested for, or undetectable. The current protocols, and likely any affordable and workable process, virtually guarantee that adulterated horse meat would travel through the slaughterhouses without detection, if the requested rules are not put in place.

[226] FDA Directive 7371.006, *supra* Note 101, at 10 (emphasis in original).

[227] *See id.* at 18.

great number of circumstances that the FSIS will never be able to identify, and that involve animals whose meat is destined for human consumption.

The FSIS is currently – even before any horses are added to the slaughter lines – unable to adequately monitor most animals slaughtered for human consumption in a manner that provides any assurance of a safe food supply. According to a 2010 report from the USDA's Office of the Inspector General, the FSIS NRP for cows was not "accomplishing its mission of monitoring the food supply for harmful residues."[228] Not only did the FSIS, FDA, and EPA fail to establish thresholds for many dangerous substances which have been found in meat, but the FSIS failed to recall meat when tests confirmed the presence of excessive amounts of veterinary drugs.[229] According to the Report, the FSIS' failure to recall adulterated beef makes it clear that the responsible federal agencies must strengthen preventative controls over contaminated animals currently traveling through the system.[230] Consequently, the Inspector General made multiple recommendations to the FSIS, FDA, and EPA, including the following: improve coordination among the agencies, develop plans to ensure adequate resources for the NRP, improve sampling and testing methodologies, canvass the drug industry and other experts for new substances to test for, develop incentives to prevent slaughter facilities from releasing potentially adulterated meat and to get plants to voluntarily trace and recall tainted meat, and modernize the testing process.[231]

The lack of a reliable identification system for food animals further hinders the ability of the FSIS to perform its mandate. In noting that a significant portion of violations results from slaughter facilities purchasing animals from sources with a history of providing animals with "drugs in their system," the Report recommended that slaughter plants be required to identify the

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[228] USDA Office of the Inspector General, Audit Report 24601-08-KC, FSIS National Residue Program for Cattle ("*OIG Report*"), p. 1 (2010), *available at* http://www.usda.gov/oig/webdocs/24601-08-KC.pdf (attached hereto as Exh. 49).

[229] *Id.* at 1.

[230] *Id*. *at* 28.

[231] *Id*. at 5-6.

producers of their cows.[232] Without knowledge of the cows' origins, the inspectors are unable to identify the source of the violation, trace the violation to the producer's practices, and preclude purchases of animals from repeat violators.[233] Thus, even with cows, raised in a regimented and highly-regulated system from birth, it is quite difficult to identify the source of adulterated animals, and meat, because the animals (especially dairy cows) pass between several buyers before their slaughter.[234] And while the FSIS recently posted a list on its website identifying suppliers of tainted cows, this list is of little use to slaughter facilities when their animals' records are insufficient or nonexistent, and because the intervening livestock auctions, sales facilities, and trading eliminate the ability to assuredly list slaughtered animals' prior owners.[235] If slaughter facilities do not receive producer identification for each animal before slaughter, they do not know which animals to subject to additional testing.[236] This failure of identification results in wasted resources and a greater likelihood of adulterated meat entering the marketplace and being purchased and consumed.[237]

This is the situation now, *without* horses in the slaughter mix. It requires no speculation to see that the facts of American horses' lives (documented in detail in Sections III.A.-D.) will decimate any possibility of adequate screening, testing, and investigation for adulterated horse meat by the FSIS under the FMIA.

4. Congress Prohibited FSIS Inspections of Horse Slaughter Plants from 2006 to 2011.

Until 2006, FSIS carried out inspections of horse slaughter plants. In an amendment to the 2006 Agricultural Appropriations Act, on November 10, 2005, Congress withdrew funding for the inspection of horses transported for slaughter, and at slaughterhouses where horses were

[232] *Id*. at 26-27.
[233] *Id*. at 27.
[234] *Id*. at 27
[235] *Id.*
[236] *Id*.
[237] *See id.*

going to be slaughtered for human consumption.[238] This was intended to effectively end horse slaughter for human consumption in America.[239] The funding prohibition was reinstated annually through 2011.

The horse slaughter industry first responded by trying to circumvent the Congressional act, working together with the FSIS to establish a set of "fee-for-service" inspections, which would allow the slaughter to continue.[240] Even though Congress plainly wanted to end horse slaughter in America, not just save some money, the slaughterers convinced FSIS to take their money and continue the inspections.[241]

The fee-for-service program did not last. First a federal court held that the program was invalid,[242] once again ending horse slaughter for human consumption in America. In 2007, the last three American facilities slaughtering horses for human consumption were shut down,[243] and in 2008 the fee-for-service inspections formally ended when Congress withdrew funding even for that program.[244]

Since 2006, when the in-country commercial processing of horses for human food production in America was prohibited, American horses have continued to be turned into meat. Trucked across the borders, American horses are now slaughtered for meat in Canadian and Mexican slaughterhouses in greater numbers than before the ban on in-country slaughter. But

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[238] Pub. L. 109-97, § 794, 119 Stat. 2120, 2164 (A.R. 51).

[239] *The Humane Society of the United States v. Johanns*, 520 F. Supp. 2d 8, 19, (D.D.C. 2007); *see discussion* Note 239.

[240] *Id*. at 11. The USDA program was part of the Agricultural Marketing Act, which has been used for inspection of wild animals. United States Government Accountability Office, Report to Congressional Committees, "Horse Welfare: Action Needed to Address Unintended Consequences From Cessation of Domestic Slaughter," GAO-11-228 (June 2011) ("*GAO Report*"), at 3 n.2 (attached hereto as Exh. 50).

[241] *Id*.

[242] *Id*. at 12.

[243] *Cavel Int'l., Inc. v. Madigan, supra* Note 19; *Empacadora de Carnes de Fresnillo, S.A. de C.V. v. Curry*, 476 F.3d 326 (5th Cir. 2007).

[244] *GAO Report*, *supra* Note 240, at 3.

that could soon change, given the recent appropriation of funds for inspection of horses going to slaughter for human food purposes, discussed in more detail in the following Section.

5. In 2011, Congress Removed Its Prohibition on Inspections of Horse Slaughter Facilities

In November 2011, at least partly in response to an inconclusive report by the federal Government Accountability Office,[245] Congress removed the prohibition on funding of FSIS inspections for horse slaughter within America.[246] For the first time in approximately five years, funding is available to inspect horse slaughter operations, despite a growing national revulsion of the possibility.[247] But it is also clear that if any horse slaughter plant desires to open, or any existing facility wants to convert to begin slaughtering horses as part or all of its business, the FSIS must engage in a thorough environmental assessment process before the plant begins its horse slaughter operations.[248]

Regardless of whether slaughter of horses begins in earnest in America, Petitioners have filed this Petition because of the immediate need for rules to be adopted to remove the danger of the potential adverse health consequences described above. American horses continue to be eaten in other countries, and the FSIS should create rules to be sure we are not exporting death and disease around the globe.

6. Pending Legislation May Permanently Ban Horse Slaughter for Human Consumption

The national attention on the horse slaughter issue is indisputable. In reaction to the appropriations bill, the horse slaughter industry began to mobilize in order to begin the killing of

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[245] *See generally id*.

[246] 2011 FD H.B. 2112 (NS) (H.R. 2112).

[247] *See, e.g., ASPCA Survey*, *supra* Note 22.

[248] This issue is discussed in detail in Section V.C., *infra*. This is the holding of *The Humane Society of the United States v. Johanns*, *supra* Note 239, discussed in greater detail below. *See also* Letter from Jonathan R. Lovvorn, Senior Vice President, The Humane Society of the United States, to Secretary of Agriculture Thomas J. Vilsack (Feb. 1, 2012), *available at* http://www.humanesociety.org/assets/pdfs/horse/usda_horse_slaughter_let_020112.pdf ("*Lovvorn Letter*") (attached hereto as Exh. 51).

American horses on American soil, maybe even for Americans to consume.[249] At the same time, the opposition legislation is mounting. For example, Congress is considering a bill to end horse slaughter completely,[250] and a different bill to limit the cruel conditions of transport for horses destined for foreign slaughter.[251] Even in Canada, where horse slaughter is ongoing and big business, a bill has been introduced which would prohibit import or export of horse meat, or of horses for slaughter for human consumption, as well as the transport of horses across province borders, where the horses are to be slaughtered for human consumption.[252]

B. Federal Regulation of Horses Slaughtered for Human Consumption under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301, *et seq*.

Congress enacted the FDCA in order to guarantee the safety of food for the consuming public, and created the FDA to fulfill this purpose.[253] As compared with FSIS, the FDA agency maintains an independent and parallel set of obligations with respect to food animal and meat safety. FDA and FSIS have separate but equal responsibilities in connection with animals who will become meat, and in connection with the meat if it is produced.[254] When harmful substances are present in foods, the FDA must enact rules and regulations that provide procedures to determine which foods contain these substances or are otherwise unsafe.[255] Among other responsibilities, the FDA must approve all food additives.[256] If food additives

[249] Besides forming a group ready to begin organizing the industry, the horse slaughter proponents introduced bills like Oklahoma's HB 2758, which would allow a tax credit for construction of new horse slaughterhouses, or modification of existing slaughterhouses to accommodate horse slaughter.

[250] American Horse Slaughter Prevention Act of 2011, SB 1176/H.R. 2966.

[251] Horse Transportation Safety Act of 2011, SB 1281/H.R. 7.

[252] Bill C-322 ("An Act to amend the Health of Animals Act and the Meat Inspection Act (slaughter of horses for human consumption)").

[253] 21 U.S.C. § 393.

[254] FDA Directive 7371.006, *supra* Note 101, p. 6.

[255] 21 U.S.C. at § 342.

[256] *See id.* at § 348; *see also* 21 C.F.R. § 570.38 (explaining the process for determining whether a substance is a food additive); FDA Food Additive Status List, (H.H.S. 2012), *supra* Note 171.

cannot be safely used, then the FDA must prohibit their presence in food or remove the offending products from the marketplace.[257]

The FDA also must identify and distinguish between drugs which are allowed, and prohibited, for use in animals that will be slaughtered for meat.[258] For example, 21 C.F.R. Sections 520.23-520.264 list dosage limits for drugs administered orally to animals. Many of the drugs listed have *no* dosage limits because they are completely prohibited and can never be administered to animals intended for human consumption. Exhibit 1 to the Petition provides a list of dangerous, unsafe, or potentially harmful drugs, many of which fall into the "completely prohibited" category; that is, once a horse has been treated with one of these chemicals, that horse can *never* be used for meat, because of the potential dangers to consumers. As previously mentioned, phenylbutazone has five different regulations prohibiting its use in animals who become food.[259] A large number of animal drugs regulated by the FDA and included on Exhibit 1 simply cannot, under any circumstances, be administered to animals slaughtered for human consumption. Exhibit 1 includes notations of over fifty drugs that have been so identified. As explained above, most of these drugs are commonly given to companion horses and horses used in sport and competition, throughout their lives, without consideration of their ultimate end as meat.[260]

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[257] 21 U.S.C. §§ 331(a)-(c), § 348.

[258] *See, e.g.*, 21 C.F.R. §§ 520, 522, 524, 526, 529; FDA Green Book On-Line, (H.H.S. 2012), *available at* http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm042847.htm (attached hereto as Exh. 52).

[259] *See* 21 C.F.R. § 520.1720a (tablets and boluses of phenylbutazone cannot be used "in horses intended for human consumption"); *id*. § 520.1720b (granules: "Treated animals should not be slaughtered for food use."); *id*. § 520.1720c (paste: "Do not use in horses intended for human consumption."); *id*. § 520.1720d (gel: not for animals used as food); *id*. § 520.1720e (powder: cannot be used on horses used for human consumption).

[260] Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

1. Horse Meat is Adulterated under the FDCA and Cannot Be Sold Legally.

The FDA, like the FSIS, is tasked within its own regulatory sphere with keeping harmful foods from the consuming public.[261] And like the FSIS, the FDA prohibits "adulterated" foods, which are unsafe and cannot be sold to the public.[262] The FDCA establishes the FDA standard for adulteration and the basis upon which the FDA may make a finding of adulteration.[263] Food is adulterated if, among other reasons, "it is or if it bears or contains . . . any food additive that is unsafe" or if it contains "any new animal drug (or conversion product thereof) that is unsafe" or "if it is otherwise unfit for food. . . ."[264] For purposes of the FDCA, a food "additive" is, broadly, any substance that may be used in such a way that it becomes a component part of the food, unless (1) the substance is already generally recognized as safe; or (2) it is one of the substances enumerated in the statute, 21 U.S.C. § 201(s), including a "new animal drug." Specifically, a food "additive" is

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . , if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures to be safe under the conditions of its intended use.[265]

[261] The Food Safety Modernization Act ("FSMA"), a part of the FDCA, adds a further level of protection under FDA's jurisdiction. Pub. Law 111-353 (2011); 21 U.S.C. § 350c, *et seq.* The FSMA amends the FDCA and "aims to ensure the U.S. food supply is safe by shifting the focus of federal regulators from responding to contamination to preventing it." FDA, "About FSMA," *available at* http://www.fda.gov/Food/FoodSafety/FSMA/ucm247546.htm (last accessed March 22, 2012) (attached hereto as Exh. 53). To that end, the FSMA contains a number of provisions aimed at improving FDA's ability to stop food safety problems before they occur, by constructing additional safeguards at the level of food manufacturing, packaging and processing plants. In the context of horse slaughter, this will entail registration of horse slaughter facilities and the creation of special protocols and procedures just for those operations.

[262] 21 U.S.C. §§ 331(a), 342.

[263] *Id*.; *see also id*. § 348 (establishing the process for regulating food additives); 21 C.F.R. § 570.38(r).

[264] 21 U.S.C. § 342(a)(2)(C)-(a)(3); *see also id*. § 348 (food additives); § 360b (new animal drugs).

[265] *Id*. § 321(s).

"New animal drugs" are defined as drugs intended for use for nonhuman animals that are not "generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof."[266]

Horse meat that contains an additive or comes from a horse that was treated with a new animal drug is presumed unsafe under the FDCA, and its sale is prohibited unless the FDA has expressly approved all the additives or new animal drugs that may be present in the meat.[267] If a food like horse meat contains an additive, the FDCA *automatically* deems it unfit for human food unless there is in effect a regulation prescribing the conditions under which the additive may be safely used and the additive is used in conformity with that regulation.[268] Similarly, if horse meat contains a new animal drug, it is *automatically* deemed adulterated and unsafe unless there is in effect an approved application for use of the drug and the use conforms to the approved application.[269]

For food additives and new animal drugs to be approved by the FDA, they must satisfy a myriad of procedural requirements (described in the following text) prescribed by FDCA and FDA regulations. Any person may petition the Secretary of the Department of Health and Human Services ("HHS Secretary") for issuance of a regulation prescribing the conditions under which an additive may be safely used.[270] The HHS Secretary may not issue a regulation until determining that the proposed use of the food additive will be safe, based on consideration of the probable consumption of the additive, the cumulative effects of the additive in the diet of persons and animals, and other safety factors used by experts in reaching such conclusions.[271]

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[266] *Id*. § 321(v)(1); *see also id*. § 360b(a)(1). *See supra* Note 177, for detailed discussion of "GRASE" products.

[267] *See* 21 U.S.C. § 342(a) (food additives); § 360b(a)(1) (new animal drugs).

[268] *Id*. § 348(a)(2). Other exceptions (irrelevant to the issues raised in the Petition) exist for additives "intended solely for investigational use by qualified experts" and additives that are "food contact substances." *Id*. § 348(a)(1), (3).

[269] *Id*. § 360b(a)(1)(A). Exceptions also exist for conditionally approved applications, which are available only for "a minor use or a minor species," *id*. § 360ccc, neither of which are at issue here. *See id*. § 360b(a)(B)-(C); *id*. § 321(oo) (horses are not a "minor species").

[270] *Id*. § 348(b)(1).

[271] *Id*. § 348(c)(3)(A), (c)(5).

Similarly, any person may file an application with the HHS Secretary for use of a new animal drug.[272] If the HHS Secretary makes any one of nine types of findings, including findings of inadequate testing, inadequate methods of production, inadequate information in the application, lack of proof of safety, or inducement of cancer, the HHS Secretary must deny the application.[273]

2. The FDA Screens Animals for Exposure to Banned Substances.

The FDA has jurisdiction over the safety of all food sold to the public, including meat and the live animals[274] who will become meat.[275] The FDA conducts investigations of potentially harmful residues in animals who will be used for food, including new animal drugs, to determine the parties responsible for any tissue residue violation and for introducing the adulterated food into interstate commerce.[276]

According to the FDA, most violations involving illegal drug residues result from animal producers' failure to comply with label warnings, such as those absolute prohibitions on the use of certain drugs for food animals identified in Exhibit 1, and their use of drugs for unapproved

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[272] *Id*. § 360b(b)(1).

[273] *Id*. § 360b(c)(1). For detailed procedures on new animal drug applications, see 21 C.F.R. § 514.

[274] *See* 21 U.S.C. § 321(f)(1), (3) (defining "food" to include "articles used for food or drink for man" and "articles used for components of any such article"); *Otis McAllister & Co. v. U.S.*, 194 F.2d 386, 387 (5th Cir. 1952) (holding that unprocessed coffee beans are food); *United States v. Tuente Livestock*, 888 F. Supp. 1416, 1423 (S.D. Ohio 1995) (holding that the FDA has the authority under the FDCA to inspect live hogs).

[275] 21 U.S.C. § 679 (declaring that the FDA has the full authority conferred by the FDCA to regulate food, notwithstanding the FMIA's conferral of authority over meat inspection to the USDA and FSIS). The FDA and FSIS share responsibility for the safety of meat, including horse meat, intended for human consumption, and it is the FDA that is responsible for ensuring that meat is safe before, and once, it enters the marketplace. *See* , *e.g.*, FDA Directive 565.100, FDA Jurisdiction Over Meat and Poultry Products (H.H.S. 2005), *available at* http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074588.htm (attached hereto as Exh. 54) (explaining that food additives used in meat are subject to both FDA and USDA jurisdiction); FSIS Factsheet, Additives in Meat and Poultry Products (USDA 2008), *available at* http://www.fsis.usda.gov/Factsheets/Additives_in_Meat_&_Poultry_Products/index.asp (attached hereto as Exh. 55) (explaining that the FSIS and FDA share responsibility for the safety of food additives used in meat); FDA Directive 7371.006, *supra* Note 101, at 49, 50 (prescribing guidelines for FDA inspection of food animals).

[276] FDA Directive 7371.006, *supra* Note 101, p. 6.

purposes.[277] Consequently, the FDA focuses on obtaining evidence of "poor husbandry practices," which would presumably include the use of substances prohibited for use in food animals.[278]

In conducting on-site investigations of potentially harmful residues in animals intended for human consumption, the FDA focuses mainly on repeat violators.[279] If resources allow, the FDA also conducts on-site inspections of first-time violators in response to FSIS reports of violative tissue residues demonstrating(1) the presence of particularly dangerous drugs in food animals, (2) the intentional misuse of a drug, or (3) a complete disregard for the withdrawal period (the "criteria").[280] If the FDA is aware of an initial residue violation but the violation does not satisfy the above criteria, FDA does not investigate.[281] Thus, FSIS is essential to preventing the dissemination of dangerous meat to the public.

3. The FDA Will Be Unable to Properly Screen Horses and Horse Meat for Exposure to Banned Substances.

As discussed in Section V.B. with respect to the FSIS, if horses are slaughtered for human consumption, it will be incumbent on the FDA to inspect the horses and their meat to ensure food safety. But success at the task will be unattainable. FDA procedures simply cannot meet the challenge, because of the untold number of exposures experienced by each horse going to slaughter, and the laundry list of prohibited and dangerous drugs to which they may have been exposed. As established above, current FDA protocols are inadequate to ensure the safety of horse meat. That is because, unlike most other animals inspected by the FDA for tissue residue violations, American horses are not raised as food, are not overseen by anyone familiar with drug prohibition and the danger of certain drugs, and their intake and exposure to drugs and other chemicals is not adequately monitored.

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[277] *Id*.

[278] *Id.* at 19.

[279] *Id.* at 10.

[280] *Id*.

[281] *Id.* (emphasis in original).

Moreover, the FDA's requirement to identify evidence of, and sanction, "poor husbandry practices," presents another insurmountable barrier with horses, as opposed to all the other species raised for human consumption.[282] Poor husbandry practices, including indiscriminate use of prohibited drugs, are certainly a cause of concern with horses as with other animals inspected by the FDA. But violations of FDA regulations will go unnoticed and forever unknown with respect to horses. Because horses are not in the market stream for most of their lives, they will be given substances unsafe for human consumption throughout their lives, while they are owned by people who do not consider their horses to be potential food. In short, the important evidence FDA needs to make its evaluations will be plainly inaccessible for horses going to slaughter.

C. Establishment of Horse Slaughter Plants Requires Environmental Review Under The National Environmental Policy Act

The National Environmental Policy Act ("NEPA") is the "basic national charter" for protecting the environment, intended to minimize risk to human health and safety, assure beneficial uses of the environment without degradation, and balance resource uses with high standards of living.[283] NEPA ensures consideration of these policy goals by requiring federal agencies to follow certain procedures in evaluating the environmental consequences of their projects prior to taking action.[284] Because of the exceptional potential for disruption of the environment caused by horse slaughter facilities, NEPA review is mandated for the establishment of new horse slaughterhouses, as well as for the conversion of existing slaughterhouses, currently processing other species, into operations involving horses.

Agencies generally must include an environmental review for every recommendation for "major Federal actions significantly affecting the quality of the human environment."[285]

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[282] *See* FDA Directive 7371.006, *supra* Note 101, pp. 19-20.

[283] 42 U.S.C. § 4331, *et seq.*; 40 C.F.R. § 1500.1.

[284] *See* 42 U.S.C. § 4332(2)(C); *City of Alexandria, Va. v. Slater*, 198 F.3d 862, 866 (D.C. Cir. 1999).

[285] 42 U.S.C. § 4332(C); *Humane Soc. of U.S. v. Johanns*, 520 F. Supp. 2d 8, 19 (D.D.C. 2007). Under the most rigorous type of review, an agency must prepare an Environmental Impact

(Footnote continued on next page)

"Actions" include adoption of official policy, such as rules and regulations, and approval of specific projects – like horse slaughter facilities – by permit or other regulatory decision.[286] Whether an action "significantly" impacts the environment depends on "context" and "intensity," including its effect on public health and safety and the degree to which the effects are controversial, among other factors.[287] Agency action "affects" the quality of the human environment if the action is the foreseeable, "legally relevant," or proximate cause of the effect.[288]

The FSIS' actions regarding horse slaughter are major Federal actions that significantly affect the quality of the human environment because (1) as established by Exhibit 1 and the Petition, most horse meat contains chemicals that are harmful to humans,[289] (2) horse slaughter operations cannot be carried out without significant negative impacts on the local environment, including the water supply,[290] (3) horse slaughter facilities detract from the quality of life in surrounding areas,[291] and (4) horse slaughter for human consumption is controversial nationally.[292]

(Footnoted continued from previous page)

Statement ("EIS"), identifying the effect of the proposed action, unavoidable adverse environmental effects, and available alternatives, among other factors. 42 U.S.C. § 4332(C); 40 C.F.R. § 1505.2. In some circumstances, an agency need not prepare a full EIS but may determine based on an "Environmental Assessment" ("EA"), a document more concise than an EIS, that the proposed action would not have a significant impact on the environment. *Pub. Citizen*, 541 U.S. at 758-59; 40 C.F.R. § 1501.4(a)-(b).

[286] 40 C.F.R. § 1508.18(b)(1), (4).

[287] *Id*. § 1508.27(a)-(b).

[288] *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 769 (2004) (legally relevant cause); *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 774 (1983) (proximate cause).

[289] *See, e.g.*, Wood Dec., Exh. 2, ¶¶ 6-7; Larson Dec., Exh. 3, ¶ 7; Pavlis Dec., Exh. 4, ¶¶ 4-5; Parker Dec., Exh. 5, ¶¶ 7-9.

[290] Sanitation workers in DeKalb, Illinois identified the Cavel plant's effluent as especially problematic, expressly because of the presence of all the drugs and dangerous substances that horses are given, such as those in Exhibit 1, that are prohibited from use in horses used for meat. *When Slaughter Comes to Town, supra* Note 141, at 4. The efforts to eliminated the byproducts of horse slaughter – blood, entrails and body parts – have led to hundreds of violations of local wastewater and environmental laws. *Id.*

[291] *See* Section IV.F., *supra*. *See also Lovvorn Letter, supra* Note 248.

[292] *ASPCA Survey, supra* Note 22.

In the *Johanns* case, the court held that "the environmental effects of horse slaughter operations themselves should have been assessed pursuant to NEPA. . . ."[293] That court's conclusion that the establishment of a horse slaughter facility merited environmental review is especially notable, because that case did not even address the core and compelling environmental concerns raised by this Petition. That is, the *Johanns* court did not have any information before it regarding the uncontrolled administration of prohibited and dangerous drugs and substances to horses throughout their lifetimes. Specifically because of the multitude of drugs given to horses during their lifetimes, both their meat and the waste created by horse slaughter creates a significant potential for a negative impact on both the environment and public health and safety. Thus, that court's determination is greatly amplified and underscored by the facts presented here: that horse slaughter involves the dissemination of an endless array of drug residues in virtually every slaughtered animal which represents an undeniable basis for triggering NEPA review. Building on the prior ruling, NEPA clearly mandates that slaughter facilities cannot begin slaughtering horses for human consumption until the FSIS prepares an EIS or EA for each facility.[294]

NEPA review is also required, as a separate matter, because the renewal of horse slaughter operations, if it occurs, will result in a change of the status quo, which is that horse slaughter has been prohibited and currently is not occurring on American soil.[295] FSIS issuance of updated rules to ensure the efficient execution of the FMIA, and FSIS approval of horse slaughter facility permit applications, if adopted, will constitute a new regulatory framework.[296]

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[293] *Johanns*, 520 F. Supp. 2d at 27.

[294] *See, e.g., id.* at 38.

[295] *See id.*

[296] *Id.*

D. European Union Laws on Horses and Horse Meat Demonstrate the Dangerous Nature of Horse Meat from American Horses

1. The European Union's Regulations Meant to Ensure the Safety of Horse Meat Illustrate the Inadequacy of American Law.

Because horses in most countries, including the United States, are not raised for food production, nations whose citizens do consume significant amounts of horse meat are concerned that imported horses and horse meat may be unsafe. In the European Union, considerable restrictions are placed on such imports.[297] In order to protect public health and avoid environmental contamination, in May 2009 the European Parliament and the Council of the European Union ("EU") adopted a regulation with respect to the importation of food-producing animals and their meat.[298] This regulation bans horse meat from horses that have been treated with any of a list of identified prohibited substances. The regulation also establishes maximum residue limits of pharmacologically active substances permitted in food-producing animals, and sets up procedures for testing those animals to ensure compliance with the regulation.[299] Pursuant to this regulation and related regulations and directives, countries exporting horses and horse meat to the EU must submit to the European Commission (the "Commission") (1) a "residue control plan" setting out guarantees equivalent to those applicable to EU member states and (2) an "action plan" with information sufficient to assess whether the importer has implemented specific measures to ensure that it does not export any contaminated animals or meat.[300]

This rule is supposed to apply to any horses for human consumption, or horse meat, sent from the U.S. and destined for the EU market. At this point, the U.S. has not put a system in place to comply with the EU requirements for an action plan. As discussed throughout the

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[297] *Residues of Veterinary Products, Third Countries*, Europa Website, *available at* http://ec.europa.eu/food/food/chemicalsafety/residues/third_countries_en.htm ("*Residues of Veterinary Products*") (attached hereto as Exh. 56).

[298] Council Regulation 470/2009, 2009 O.J. (L 152) (EC) (attached hereto as Exh. 57).

[299] *Id*. at 11, 14-15.

[300] The former requirement is derived from a 1996 Council Directive (96/23/EC), whereas the latter was established in the 2009 Regulation.

Petition, the U.S. probably cannot comply with the EU requirements because of the sources from which the American horses who become meat originate, and the impossibility of providing the required proof of medical, and medication, history.

In its residue control plan, the U.S. will be required to submit to the Commission a description of how it will ensure that horse meat and horses meant for human consumption that enter the EU market meet safety standards at least as stringent at those applicable within the EU. The EU explicitly prohibits importation of horses and horse meat that fail to meet these standards.[301]

Many of the drugs listed on Exhibit 1 to the Petition, which are regularly used on American horses without documentation, are also "prohibited substances" in the EU.[302] If American horses have ever been exposed to these substances, as well as other identified classes of drugs (certain steroid hormones and beta-agonists used for growth purposes), those horses need to be completely excluded from the food supply.[303] The Commission will only approve America's new residue control plan if the U.S. establishes a "split system" to separate horses who have been treated with those substances from those destined for export to Europe.[304] Because there is no such system in place, and because there is no way of controlling the use of these substances, meat from American horses cannot legally enter the EU or be sold there at this point in time.

If American exporters are to comply with the EU's requirements, the U.S. will need to enact detailed new legislation and regulations that meet the EU standards and govern authorization, distribution, and provision of veterinary products that may be used on all horses, at

[301] Council Directive 96/22/EC, art. 11 (2), 1996 O.J. (L 125) 3, 7 (EC) (attached hereto as Exh. 58); Council Directive 96/23/EC, art. 29, 30, 1996 O.J. (L 125/10) (attached hereto as Exh. 59).

[302] *See* Commission Regulation (EU) No. 37/2010, Table 2 (prohibited substances include chloramphenicol, chloroform, colchicine, metronidazole).

[303] Council Directive 96/22/EC, Annexes II, III. *supra* Note 306.

[304] Council Directive 96/22/EC, art. 11 (2), 1996 O.J. (L 125) 3, 7 (EC), *supra* Note 306; *Residues of Veterinary Products, supra* Note 302.

all stages of their lives. The actual U.S. "residue control plan" will have to be submitted to the EU and must include five general elements. First, the plan must describe how the U.S. will assign the coordination and implementation of inspections to a central governmental agency that will be responsible for monitoring, data collection, and data submission to the Commission.[305] Second, the U.S. must describe for the Commission the laws governing veterinary medical products.[306] Third, the plan must list approved laboratories for residue controls, as well as the accreditation status of these laboratories.[307] Fourth, the plan must describe the rules covering collection of official samples.[308] Finally, the plan must contain details on measures to be taken in the event of infringement of the U.S. pharmacological substance limits and inspection regime.[309]

In addition to establishing a residue control plan and monitoring its results, the U.S. will also need to submit to the Commission an action plan explaining how it will implement several measures to prevent the export of unapproved horse meat. The U.S. will need to make significant changes to its regulatory framework governing the treatment, identification, and inspection of horses slaughtered and intended to be slaughtered for human consumption before resuming exportation of horse meat to the EU.

In order to comply with the EU's requirements, the U.S. must have in place or implement the five following measures. First, the U.S. must establish an identification and verification system for *all* horses intended for food production.[310] Second, horses given anabolic steroids for growth purposes, and other prohibited substances, must be identified and segregated from horses to be exported to Europe for human consumption.[311] Third, only horses with known medical

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[305] Council Directive 96/23/EC, art. 4, 1996 O.J. (L 125) 10, 12 (EC), *supra* Note 306).
[306] *Id*. art. 7 (1), 1996 O.J. (L 125) 10, 13 (EC).
[307] *Residues of Veterinary Products, supra* Note 302.
[308] Council Directive 96/23/EC, art. 7 (6), 1996 O.J. (L 125) 10, 13 (EC) *supra* Note 306.
[309] *Residues of Veterinary Products, supra* Note 302.
[310] *Id*.
[311] *Id*.

treatment histories may be slaughtered and exported to Europe as consumer-grade meat.[312] All horses must be accompanied by an identification document, which the Commission calls "passport," on which each horse's owner records all veterinary medical treatments received by each horse.[313] While the EU has given the U.S. and other horse and horse meat exporters a three-year transition period in which veterinary records need only guarantee that a horse has not been administered a banned substance (something the U.S. cannot even do now, as explained in the Petition), by 2014 all horses meant for human consumption in Europe must be accompanied by medical treatment records which span their entire life. Fourth, the U.S. must guarantee that each horse slaughtered for human consumption has never received banned substances and is free from restricted substances for the required withdrawal periods.[314] And fifth, the U.S. must regularly inspect collection centers and slaughter facilities to ensure that exporters are adhering to EU regulations on the use of veterinary products and banned substances.[315]

It is unfathomable that the U.S. regulatory regime will ever be able to track horses' lifetime medical records. American suppliers do not and cannot meet the treatment, identification, and inspection requirements established by the EU. It is impossible, based on current testing and verifications protocols, for the U.S. to guarantee that horses treated with banned or restricted substances do not enter the food supply.[316] As demonstrated by Exhibit 1 and discussed elsewhere in the Petition, hundreds of substances are banned in all animals intended for human consumption, but there is no "pre-slaughter mechanism" to identify and

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[312] *Id*.

[313] *Id*.

[314] *Residues of Veterinary Products, supra* Note 302.

[315] *Id*.

[316] *See, e.g., Phenylbutazone Health Risks*, *supra* Note 106. *See also* European Commission Food and Veterinary Office, Final Report of an Audit Carried Out In Canada From 23 November to 6 December 2010, Ares(2011)1101887, 12-16 ("*Canada Report 1*") (attached hereto as Exh. 60); European Commission Food and Veterinary Office, Final Report of a Mission Carried Out in Mexico From 22 November to 3 December 2010, Ares(2011)398056, 6-9 ("*Mexico Report*") (attached hereto as Exh. 61); European Commission Food and Veterinary Office, Final Report of an Audit Carried Out In Canada From 13 to 23 September 2011, Ares(2012)257268 ("*Canada Report 2*") (attached hereto as Exh. 62); *infra* Section VI.B.5.

exclude horses who have been exposed to those substances from the food supply.[317] Even if the U.S. enacts a myriad of regulatory measures to try to conform to EU regulations, it will surely fall short of the mark set by the EU, which would require the tracking of every horse sent for human consumption from the date of their birth. Because virtually no horses in America are identified as potential meat until late in their lives, when it is not feasible or possible to trace backwards, only a crystal ball can solve this problem. This bar with respect to the EU requirements is also a clear illustration of the inadequacy of current rules and regulations to protect consumers of horse meat from significant danger.

2. Certification of Horses Exported to Mexico and Canada for Slaughter under European Rules is Unreliable and Threatens the Food Supply.

Since 2007, over 100,000 American horses have been exported to slaughter facilities in Canada and Mexico each year. Those two border countries exponentially increased their imports of American horses in response to the defunding of FSIS inspections discussed in Section V.A.4. Most of the horses slaughtered in Canada and Mexico are sold to overseas markets in Europe and Asia, where horse meat is an expensive commodity. As exporters of horse meat to EU nations, the Canadian and Mexican slaughterhouses have presumably made efforts to comply with the EU regulations just discussed, which restrict imports based on the prior exposure of the horses to a variety of substances including many of those on Exhibit 1 to the Petition, as well as on the quality of the meat. But the border countries' efforts have not been enough to meet the reasonable European standards. Neither can American agencies like FSIS, which are intended to protect the consuming public from health problems arising as a result of eating problematic horse meat, fill the gap in information that jeopardizes the food supply.

The Commission recently published the results of audits undertaken in order to evaluate Canadian and Mexican compliance with EU regulations. These audits revealed that both

[317] In a recent study of phenylbutazone treatment of thoroughbred race horses, eighteen of eighteen thoroughbred horses intended for slaughter for human consumption tested positive for phenylbutazone. *Phenylbutazone Health Risks*, *supra* Note 106, at 1271. In the five-year period over which the authors examined data, over 90,000 thoroughbred race horses were sent to slaughter. *Id.*

countries' controls over the production of horse meat are inadequate to protect consumers.[318] In particular, the auditors criticized both Canada and Mexico for relying on a system that permits the American killer-buyers, typically the last owners of American horses, to certify that the horses they are selling have never been administered banned veterinary drugs and other harmful substances without providing medical records or any kind of formal guarantee.[319] This inadequate certification system, which is an unavoidable consequence of slaughtering American horses, results in the export of tainted horse flesh from the United States, through Canadian and Mexican slaughter facilities, to EU consumers.

Though almost all horses raised in the United States are administered substances listed in Exhibit 1 which render their flesh unsafe for human consumption, Canada and Mexico continue to import these horses, slaughter them, and export their meat to foreign nations. As discussed in the prior Section of the Petition, the EU currently requires horses raised in EU member states and intended for human consumption to be accompanied by a "passport," which identifies the animal's complete medical history, including the administration of veterinary drugs.[320] And (until 2014) the EU requires Americans who sell horses to Canadian or Mexican parties for slaughter to issue a declaration stating that (1) no drug or other substance that the EU prohibits for use on food animals has ever been administered to the horse and (2) withdrawal limits for other drugs administered to their horses have been met.[321] Even this limited standard provides no protection, because the person making the certification is the horse's last owner – often an individual who purchased the horse only a few days before the sale, and who bought the horse

[318] *Canada Report 1*, *supra* Note 321; *Mexico Report*, *supra* Note 321, 6-9; *Canada Report 2*, *supra* Note 321 (stating that "for those horses imported from the United States of America for direct slaughter, the equine identification documents received were not reliable, with verification only being possible by means of residue testing.") All U.S. horses imported into Canada were for direct slaughter. *Id.* at 29. Notably, of the 30,000 horses slaughtered in Canada in 2011, 85% were from the U.S., 90% of slaughtered horses were exported, and half of all horse meat exported went to the EU. *Id.*

[319] *See generally Canada Report 1, supra* Note 321; *Mexico Report, supra* Note 321.

[320] *See* Section V.D.1, *supra; Residues of Veterinary Products, supra* Note 302.

[321] *See id.*

solely for the purpose of selling for slaughter. That recent purchaser issues an affidavit to accompany the horse in which he declares that the horse has not been administered any banned substances – but those statements are often made without knowledge of their accuracy.[322] These assertions are also made, without confirmation, by a party whose primary interest is in being able to sell the horses for profit, and whose profit would disappear if the horses had ever been administered any of the prohibited substances. And even if the final purchasers/sellers are able to provide an accurate statement regarding their knowledge of the horses' exposure to certain drugs, they cannot possibly know what drugs the horses were given over the course of their lives. Since it is a known fact that many of those drugs and substances render the horses' meat *permanently* unfit for human consumption, the system of sending American horses for slaughter, in its present form, is hopelessly, and almost irreparably, flawed and dangerous.

The sworn statements currently required under U.S., Canadian and Mexican law are completely insufficient to guarantee the fitness of the horse's flesh for human consumption.[323] While the FSIS issues an export certificate for each horse, which certifies the horse's identification, the FSIS does not require horse owners to maintain their medical records, guarantee the origin of the horse, or take responsibility for the accuracy or authenticity of the sworn statements.[324] And there is no system to verify or trace back the accuracy or authenticity of declarations accompanying horses who Mexican or Canadian border inspectors previously rejected for illness, later appear before the same inspectors as healthy, and may have just been treated with banned substances to overcome their recent illness.[325] Consequently, the interim system mandated by the EU and established by Canada and Mexico almost guarantees that American horses slaughtered for human consumption, who have been administered banned substances, will end up as dangerous food.

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[322] *Canada Report 1, supra* Note 321 at 15; *Mexico Report, supra* Note 321 at 7.

[323] *See, e.g., Canada Report 2, supra* Note 321, at 28 (describing exclusion of animals from European Union market who do not have complete drug histories prepared).

[324] *Canada Report 1, supra* Note 321, at 15; *Mexico Report, supra* Note 321, at 7.

[325] *See Mexico Report, supra* Note 321, at 7.

The potential for both inadvertence and fraud that will lead to unsafe food being consumed by purchasers is clear. Commission auditors have expressed concern over the lack of responsibility taken by the United States government over the safety of horse meat derived from American horses.[326] The potential for slaughtered horses to have been given significant amounts of dangerous substances is high, based on the origins of the horses, discussed in Sections IV.A-D. above.

Additionally, private individuals have also uncovered proof of fraud among Americans who sell horses for slaughter. At one horse export market selling horses to be exported to and slaughtered in Canada, blank declarations (besides signatures) were randomly matched with horses sold for slaughter; there was no actual reference to the specific horse, and no accurate information about that horse was passed along.[327] These declarations purportedly certified that the horses they accompanied had never been administered any prohibited substances when, in reality, they were prepared and applied to horses without regard to their accuracy or the identity of the horse.[328] Other individuals have witnessed auction houses complete the declarations for owners – even though the auction houses obviously knew nothing about the animals.[329] Given the lack of any viable controls on the quality of horses and horse meat being exported, the FSIS should immediately amend its policies, procedures, rules and regulations to address these issues and ensure unadulterated meat for the consuming public.

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[326] *Canada Report 1*, *supra* Note 321, at 15; *Mexico Report*, *supra* Note 321, at 7.

[327] *See Investigation on horse meat entering Europe from America*, ITALIAN HORSE PROTECTION ASSOCIATION, *available at* http://www.horseprotection.it/dett_articolo.asp?id_a=379 (attached hereto as Exh. 63); *see also* Photographs of the New Holland Auction, *available at* http://www.horseprotection.it/docs/eid/album/index.html (attached hereto as Exh. 64).

[328] *See id.*

[329] *See Pasture to Plate*, *supra* Note 127 ("After reviewing all the EIDs [Equine Information Documents] it is apparent that some auction houses are helping to complete the documents on behalf of some owners or agents. Consistent statements such as "Drug-free Six Months" in the same hand writing, and the same red pen colour, are written across the top.").

VI. STATEMENT OF GROUNDS

A. American Horses Are Unfit for Human Consumption Because They Are Not Raised for Food and Create the Potential for Myriad Health Hazards upon Ingestion of Their Flesh.

There is an important health and food safety distinction to be made between *horses* sent to slaughter and eventual human food production, and the several other, more commonly eaten species, such as cows, pigs, chickens, turkeys and sheep. Those more traditional livestock/food animals are, from before birth, raised in an environment that contemplates their growth and eventual transformation into meat products that will be consumed here and abroad. The individuals who are involved in the breeding, raising, and killing of those animals are aware, every step of the way, that the animals they are using are destined for human consumption. But this is not the case with horses, who come from a variety of factual settings, *none of which* necessarily involve contemplation of the horses' ultimate end as being human food. This fundamental distinction between horses and all other animals that humans eat creates a severe, drastically increased, and particularized danger connected to the eating of horse meat that does not exist for other food animals.[330]

The reason that horse meat carries such an escalated risk of health danger and negative consequences is, as explained throughout the Petition, that horses who eventually become meat are given multitudes of drugs over the course of their lives. The drugs given to horses lead to these health and safety concerns because of a number of considerations that may not be immediately obvious, but that are explained in this Petition and in the following sections.

1. Horses Receive Many Drugs Known to Be Dangerous.

Many drugs commonly administered to horses are proven to be unsafe for human use – so that ingestion in horse meat creates great cause for alarm.[331] These include drugs that are prohibited for use on humans, as well as those that humans take only in very controlled

[330] As discussed in Section V.A.3., *supra*, even the federal government's ability to adequately monitor the safety of those more commonly eaten, regulated-from-birth animals is limited, which may endanger the consuming public.

[331] *See* Exhibit 1; *see generally* Greger Dec., Exh. 6.

situations, with knowledge of potential severe side effects.[332] Nitrofurazone, for example is used to treat bacterial infections in horses but is toxic to humans' respiratory and nervous system.[333] Trimethoprim kills and controls bacteria in horses with respiratory tract infections; in humans, it causes a number of adverse effects and interferes with the important metabolism of folic acid, which can lead to blood dyscrasias.[334] And dexamethasone, an anti-inflammatory agent for horses, causes muscle weakness, osteoporosis, peptic ulcer, pancreatitis, growth suppression (in children), glaucoma, and weight gain in humans.[335]

These are only a few select examples from Exhibit 1. There are dozens of other drugs commonly used on horses on a regular basis, that likely cannot be identified in their tissues, and that create great danger for human use. Many, but not all, of the drugs and other substances that fit into this category have been consequently banned by the FDA for use in horses intended for human consumption. The message is clear – there is an identified significant danger if humans are exposed to these products, and the scientists responsible for making these decisions have concluded unequivocally that under no circumstance can exposure or ingestion of these products be safe. Nevertheless, because American horses *not* raised to be consumed by humans end up as horse meat, these drugs are ingested by humans who eat horse meat from American horses.

2. Horses Receive Many Drugs That Have Never Been Tested on Humans.

Other drugs commonly administered to horses *have never been tested on humans*. So while those drugs are not at this point known to be unsafe when used by humans, there is absolutely no evidence that they are safe, either. Because there has never been any expectation that humans would be exposed to or ingest these drugs, there has simply been no testing. This does not make these drugs safe; to the contrary, it makes every piece of horse meat a potential health time bomb for unsuspecting humans eating horses who have been treated with these

[332] *See* Exhibit 1; *see generally* Greger Dec., Exh. 6.

[333] *See* Exhibit 1.

[334] *See* Exhibit 1.

[335] *See* Exhibit 1.

drugs. Clenbuterol, for example, is used for growth promotion purposes in horses but has not been approved for human use.[336] Similarly, equine influenza vaccine helps healthy horses avoid contracting the equine influenza, but it is not intended for human use and has not been tested on humans.[337] A third example is n-octyl bicycloheptene disarboximide, which enhances the pesticidal properties of other active ingredients but could cause cancer in humans, based on increased rates of tumors in lab rats.[338] While it is unclear whether drugs unintended for human use are harmful when ingested by humans who consume horse meat, certainly it would be unreasonable and arbitrary and capricious for FSIS to take the risk of approving this meat, knowing it will mean that people will be ingesting drugs that are untested on, and not meant for, human consumption. Such a risk certainly makes meat containing those substances "unfit for human food."[339] The FSIS cannot treat virtually identical situations differently, and it has appropriately enacted regulations to minimize the small risk of beef that might carry bovine spongiform encephalopathy ("mad cow disease") from ever getting into the food supply. The agency cannot ignore the many potential disasters presented here, which may have an even greater chance of occurring, without acting contrary to that prior determination.

3. Even Drugs That Are Safe for Humans May Be Unsafe for Horse Meat.

Many of the drugs on Exhibit 1 – and many additional drugs given to horses regularly but not on Exhibit 1 – are also approved for human use, and may be used regularly by many humans. Amoxicillin is an antibiotic often prescribed for humans. Prednisone is a powerful steroid also used in human medicine. Many people take nonsteroidal anti-inflammatory drugs ("NSAIDs") for a variety of symptoms.[340] And while the human uses may be for the same or different reasons that they are given to horses, this categorically does *not* provide assurance that the drugs

[336] *See* Exhibit 1.

[337] *See* Exhibit 1.

[338] *See* Exhibit 1.

[339] *See* 21 U.S.C. § 601(m)(3).

[340] Other NSAIDs, like phenylbutazone, are prohibited for use by humans. *See* Exhibit 1.

are safe when given to horses, who become meat, that humans then eat.[341] First, as with any drug prescribed or recommended for humans, there will be a certain percentage of the population that has mild to severe (including fatal) allergic reactions to some drugs.[342] It is also well-known that many drugs, such as the commonly used antibiotics, are safe for most individuals under most conditions; but for humans with allergies or drug sensitivities to those antibiotics (for example, penicillin), these drugs can lead to anaphylactic shock, injury and even death.[343] Therefore any meat that comes from an animal who may pass on that drug could lead to terrible effects on consumers.[344]

Thus, even the substances commonly administered to horses that are FDA-approved for use in humans could be harmful to some humans who ingest them.[345] If drugs are invisibly present in horse meat, and people eat them unknowingly, the meat (and the hidden drugs) may cause significant harm.[346] These otherwise approved drugs can be problems because there is a substantive distinction between a doctor intentionally recommending a drug for an identified problem, after evaluation of her patient and the presenting issue, and that same person not having a problem, not talking to a doctor, and unintentionally and unknowingly ingesting a drug embedded in horse meat.

Sucralfate, for example, is commonly administered to horses and approved for use in humans for short-term treatment of ulcers – but it may cause humans numerous adverse reactions, including diarrhea, pruritus, rash, and dizziness.[347] Similarly, humans may use

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[341] *See* Exhibit 1; Greger Dec., Exh. 6.

[342] Greger Dec., Exh. 6, ¶¶ 5-6.

[343] *See id.*

[344] *See id.*

[345] *See* Exhibit 1; Greger Dec., Exh. 6.

[346] Even aspirin, routinely used and prescribed, can cause hives, facial swelling, asthma, and shock when ingested by someone allergic to it. *See* Exhibit 1. Cimetidine, also used by humans, can cause a series of unpleasant sequelae, and other drugs may cause bleeding in those humans who have particular susceptibilities or immune-mediated conditions affecting the blood system. *See* Exhibit 1.

[347] *See* Exhibit 1.

praziquantel, which is commonly administered to horses to treat worm infections near the liver, but praziquantel may cause dizziness, fever, nausea, and hives.[348] Horses may also be given drugs which affect the clotting mechanisms; if people with blood disorders ingest even a small amount of such substances, the consequences could be tragic. Just because these drugs are useful to some humans under some conditions does not make them safe when present in horse meat that will be consumed by humans who are not aware of their presence, and who are unprepared to deal with the drug's adverse reactions or unexpected and unknown allergic reactions. In short, it depends on the individual: drugs that are safe when taken by most individuals are unsafe when taken by those same individuals under certain conditions and unsafe when taken by other individuals under any conditions.[349]

In addition to the potential allergic responses, many drugs ingested by humans who consume horse meat may ordinarily be safe for human use, but may be especially dangerous upon interaction with other drugs commonly taken by humans.[350] Physicians routinely inquire about medications patients are currently taking before prescribing new medicine, because many drugs have the potential to combine with, exaggerate the effects of, or nullify other medications.[351] The dangers of taking two different drugs without consulting a doctor are well understood. But because there is no way of controlling what drug residues might be in horse meat, and because there is such a wide variety of potential drugs in horse meat, it must logically be considered unfit for human food.

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[348] *See* Exhibit 1.

[349] Greger Dec., Exh. 6, ¶¶ 5-9. And while small doses of drugs unexpectedly ingested by at-risk individuals may not initially cause them harm, the accumulation of small doses of these drugs over time can cause problems that a single small amount usually would not. This, too, depends on the individual. *Id*.

[350] Greger Dec., Exh. 6, ¶ 4. Hydroxyzine pamoate, for example, becomes more potent when taken by someone who also takes antidepressants. *See* Exhibit 1.

[351] Greger Dec., Exh. 6, ¶ 4.

B. Horse Meat Containing Certain Food Additives and Veterinary Drugs Is Adulterated and Unsafe for Human Consumption.

As established above, most of the horses who end up being slaughtered for meat are of three identified types – companion horses (including pleasure and work functions), horses involved in sports and competitions, and wild horses who are funneled into one of those first two categories – and the use, by those horses, of the drugs and substances listed in Exhibit 1 is widespread among all three groups. As also established above, the indiscriminate use of substances listed in Exhibit 1 occurs because the owners of the horses who end up in production for meat have no intention or expectation that their horses will someday be food. Accordingly, virtually all horse meat is "adulterated" under the FMIA because (1) many of the substances listed in Exhibit 1 are explicitly banned as unfit for use in horses intended for human consumption, and thus any horse who has had those substances cannot legally be used for meat,[352] (2) many of the substances listed in Exhibit 1 are food additives declared unsafe by the FDA,[353] (3) horses often contain animal drug residues, including those listed in Exhibit 1, in amounts exceeding FDA tolerance levels,[354] and (4) other substances listed in Exhibit 1, some of which are approved for use for humans, can be harmful to humans who ingest them, depending on a variety of factors that cannot be predicted, controlled for, or eliminated in the class of individuals who may be horse meat consumers.[355]

Therefore, virtually all horse meat is unfit for food and cannot be transported or sold for human consumption under the FMIA without (1) an overhaul and infusion of significant

[352] *See* 21 U.S.C. § 601(m)(2)(C), (m)(3); 21 C.F.R. §§ 520, 522, 524, 526, 529 (prohibiting the use of dozens of "new animal drugs" in animals intended for human consumption as unsafe); Exhibit 1.

[353] *See* 21 U.S.C. § 601(m)(2)(C) (adopting the FDCA provision on food additives, 21 U.S.C. § 348); *id*. § 348 (declaring food additives unsafe unless "there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used. . . ."); Exhibit 1.

[354] *See* 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA); Exhibit 1.

[355] *See* 21 U.S.C. § 601(m)(2)(C) ("unfit for human food"); § 601(m)(1) ("may render it injurious to health"); Exhibit 1.

resources for the National Residue Program ("NRP") to provide for the systematic inspection of horses for whom there is reason to believe that a violative residue is present and (2) adequate monitoring and oversight of the horses who become meat, including a reliable lifetime history of each horse's exposure to drugs, treatments, and other potentially harmful substances.[356]

1. The Variety of Drugs Administered to American Horses Makes Their Meat Adulterated and Unsafe for Human Consumption.

Virtually all horse meat derived from American horses is adulterated under the FMIA because many of the veterinary drugs listed in Exhibit 1 are unfit for use in food consumed by humans.[357] Over fifty of the substances listed in Exhibit 1 can not under any circumstances be used in horses intended for human consumption, making horse meat from horses treated with those substances adulterated and illegal as a meat product.[358] These substances are so dangerous that if any trace of them appears in a muscle tissue residue test, the FSIS automatically condemns the carcass and all parts.[359] Drugs commonly administered to horses but which may render their meat unfit and illegal include the following: boldenone undecylenate (used for physical improvement in debilitated horses),[360] butorphanol (used for pain relief),[361] ceftiofur crystalline free acid (used to treat lower respiratory tract infections),[362] ceftiofur sodium (used to treat respiratory infections),[363] and copper naphthenate (used to treat sores on the mouth and tongue).[364] This list of substances only includes drugs on Exhibit 1 beginning with the letters 'b' and 'c,' all of which are commonly administered to horses but must not be administered to horses intended for human consumption.[365] Meat from any horse that has ever been

[356] *See* discussion of NRP, *supra* Section V.A.2.

[357] *See* 21 U.S.C. § 601(m)(2)(c); 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[358] *See* 21 U.S.C. § 601(m)(2)(c); 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[359] *See* FSIS Notice 14-11, *supra* Note 170.

[360] 21 C.F.R. § 522.204(c) ("Do not administer to horses intended for human consumption.").

[361] 21 C.F.R. § 522.246(d)(3)(iii) ("Do not use in horses intended for human consumption.").

[362] 21 C.F.R. § 522.313a(e)(3)(iii) ("Do not use in horses intended for human consumption.").

[363] 21 C.F.R. § 522.313c(e)(7)(iii) ("Do not use in horses intended for human consumption.").

[364] 21 C.F.R. § 524.463(c)(3) ("Do not use in horses intended for human consumption.").

[365] *See* Exhibit 1.

administered any of the above prohibited substances, in addition to all of the other banned substances listed in Exhibit 1, "is unfit for food" and "may render it injurious to health," is adulterated, and may not be sold or transported for human consumption under the FMIA.[366]

2. The Presence of Prohibited Drug Residues in Horses Makes Horse Meat Adulterated and Unsafe for Human Consumption.

Not only is most horse meat adulterated under the FMIA due to the administration of drugs absolutely prohibited for use on horses intended for human consumption, but some of this meat is also adulterated, as a separate matter, due to the presence of excessive drug residues.[367] The FDA prohibits the administration of many of the veterinary drugs listed in Exhibit 1 to horses intended for human consumption in any amount,[368] and the FSIS has adopted the drug residue tolerance levels established by the FDA.[369] Therefore, residue tests that reveal even trace amounts of these banned substances in horses or horse meat render the meat adulterated.[370] Consequently, if traces of the above drugs from Exhibit 1 that begin with the letters 'b' and 'c' – boldenone undecylenate,[371] butorphanol,[372] ceftiofur crystalline free acid,[373] ceftiofur sodium,[374] and copper naphthenate,[375] all drugs that may not be administered to horses intended for human consumption – are found in tissue collected and tested by FSIS inspectors, all meat from that horse is adulterated.[376] The same applies to each of the other dozens of veterinary drugs

[366] *See* 21 U.S.C. § 601(m)(2)(c); § 601(m)(1); 21 C.F.R. §§ 520, 522, 524, 526, 529; 21 U.S.C. § 610(c) (prohibiting the sale, transport, offer for sale or transport, or receipt for transport of any carcasses, parts of carcasses, meat, or meat products from animals that are capable of use for food and adulterated); Exhibit 1.

[367] 9 C.F.R. § 318.20 (adopting drug residue tolerance levels established by the FDA).

[368] *See* 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[369] *See* 9 C.F.R. § 318.20.

[370] *See* 9 C.F.R. § 318.20 (explaining that drug residues in excess of FDA tolerance levels are not permitted in meat and meat food products).

[371] 21 C.F.R. § 522.204(c) ("Do not administer to horses intended for human consumption.").

[372] 21 C.F.R. § 522.246(d)(3)(iii) ("Do not use in horses intended for human consumption.").

[373] 21 C.F.R. § 522.313a(e)(3)(iii) ("Do not use in horses intended for human consumption.").

[374] 21 C.F.R. § 522.313c(e)(7)(iii) ("Do not use in horses intended for human consumption.").

[375] 21 C.F.R. § 524.463(c)(3) ("Do not use in horses intended for human consumption.").

[376] *See* 9 C.F.R. § 318.20; 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

commonly administered to horses that are prohibited for use in horses intended for human consumption.[377]

3. Food Additives Render Horse Meat Adulterated and Unsafe for Human Consumption.

Other substances listed in Exhibit 1 are food additives under the FDCA (as opposed to "new animal drugs") because they are intended or reasonably expected to become "a component or otherwise affect[] the characteristics of any food … including any substance intended for use in producing [or] manufacturing. . . ."[378] Many of these food additives are unsafe for administration to food animals under the FDCA, and consequently, adulterated under the FMIA.[379] There can be no doubt that the substances described on Exhibit 1 and throughout the Petition, once given to horses, meet the statutory definition of "additive" under 21 U.S.C. § 321(s). For example, many of the substances on Exhibit 1 are growth hormones, substances intended to alter body chemistries, or to improve body quality, muscle mass, or growth rates. Clearly they "affect the characteristics" of the meat – indeed that is their sole purpose.[380] Likewise, they are "intended for use in" the production and manufacturing of the meat, and unquestionably both directly and indirectly "affect[] the characteristics of" horse meat.[381] As a matter of food safety, they are not guaranteed as safe by scientists or by long-term usage. As such, they are food additives that are deemed unsafe under both the FMIA and FDCA.[382]

Exhibit 1 to the Petition provides an extensive list of drugs that fit this profile and render horse meat, with its guaranteed but unknown quantities of these drugs, unsafe.[383] By way of brief example, olaquindox, an antibiotic used to promote the growth of horses, is a food additive

[377] *See* 9 C.F.R. § 318.20; 21 C.F.R. §§ 520, 522, 524, 526, 529; Exhibit 1.

[378] *See* 21 U.S.C. §§ 321(s), 342(a)(2)(A); Exhibit 1.

[379] *See* 21 U.S.C. § 601(m)(2)(C) (adopting the FDA list of unsafe food additives); 21 U.S.C. § 348(a)(2) (establishing which food additives are unsafe under the FDCA); *see also* FDA Food Additive Status List, (H.H.S. 2012), *supra* Note 171.

[380] 21 U.S.C. § 321(s).

[381] *Id.*

[382] *See* 21 U.S.C. § 601(m)(2)(C) (FMIA); *id.* § 348(a)(2) (FDCA).

[383] Exhibit 1.

for which the FDA has not issued a regulation prescribing conditions under which it may be safely used.[384] Accordingly, any horse meat containing olaquindox is adulterated and cannot be sold or transported for human consumption.[385] This is just one of many on the list that similarly fit into this class.

4. The FSIS' National Residue Program Is Unable to Protect the Food Supply if Horse Slaughter Begins Again.

If American horses are slaughtered for human consumption, the FSIS will be responsible for inspecting hundreds of thousands of additional animals before and after slaughter, testing them for a vast array of drugs known to be administered to most American horses, devising new analytical methods, establishing new sampling plans, updating inspection and testing protocols, performing additional tests for tissue residue violations, and collaborating more with other agencies to accomplish their shared mission. All this will need to be done in the shadow of nationwide (and the agency's acknowledged) resource constraints, for a product that most Americans firmly detest. Even if the FSIS successfully implements these steps, it will only be able to inspect and test horses as it does other animals, based on its established programs discussed below. The FSIS has already had significant problems protecting the food supply from adulterated meat from animals who are already raised in regimented fashion to become food. For all the reasons stated in the Petition and this Section, it will be eminently more difficult for the FSIS to protect the food supply from adulterated meat from horses, who are not raised to become food and whose prior owners are not known.

FSIS, FDA, and EPA have been unable to accomplish their mission of monitoring the food supply for harmful residues in cows under the NRP; this finding calls into question their

[384] *See* 21 C.F.R. § 510.110(f) (explaining that antibiotics "are deemed to be new drugs as well as food additives"); 21 U.S.C. § 342(a), § 348 (food additives); FDA Food Additive Status List, (H.H.S. 2012) (omitting olaquindox); Exhibit 1.

[385] *See* 21 U.S.C. § 610(c) (prohibiting the sale, transport, offer for sale or transport, or receipt for transport of any carcasses, parts of carcasses, meat, or meat products from animals that are capable of use for food and adulterated); 21 U.S.C. § 601(m)(2)(C) (food additives deemed unsafe by the FDA are adulterated under the FMIA); 21 U.S.C. § 348(a)(2) (declaring, with a few irrelevant exceptions, that food additives for which there is no regulation prescribing the conditions under which they may be used safely are unsafe); Exhibit 1.

ability to do so with horses. As documented in the recent Report from the Office of the Inspector General on the NRP for cows, the FSIS failed to adequately monitor the presence of banned and limited substances in animals intended to be slaughtered for human consumption even when the agency was focused directly on those substances.[386] And the FSIS failed to recall tainted meat when tests confirmed the presence of excessive amounts of harmful substances.[387] Monitoring the known food supply is easier than monitoring the unknown food supply, but the Inspector General's Report demonstrates that the FSIS was unable to do the former adequately.[388]

Moreover, the lack of a mandatory identification system for horses, as with cattle, will make it virtually impossible for slaughter facilities and inspectors to identify the source of adulterated horse meat.[389] While identifying the source of violations in cattle is difficult enough because they are passed between several buyers before slaughter, identifying the source of violations in horses is virtually impossible. Horses are not only passed between several owners, but many of the initial owners may often be untraceable. Even if found, it is unlikely that early owners kept records of drug administration that would affect the safety of their horses' meat – because they did not intend or expect their horses to one day become food.[390] Just as livestock auctions, cattle sales facilities, and cattle traders often fail to completely list their animals' prior owners, the problem will be hopelessly compounded when adding in the unknowns of early owners of horses.[391] The federal agencies will need to expend infinite resources in the identification process, and still there will be an almost insurmountable chance that adulterated horse meat, tainted with multiple dangerous substances, will enter the marketplace and be purchased and consumed.[392]

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[386] *See* USDA Office of the Inspector General, Audit Report 24601-08-KC, FSIS National Residue Program for Cattle, *supra* Note 208.

[387] *See id.* at 1.

[388] *See id.*

[389] *See id.* at 26-27.

[390] *See id.*

[391] *See id.*

[392] *See id.*

5. FSIS Inspection and Testing Protocols Are Insufficient to Prevent the Entry of Adulterated Horse Meat into the Food Supply.

The unique nature of horse meat from American horses (given their origins and histories prior to slaughter) means that the FSIS will have to take additional steps to protect the food supply from adulterated horse meat. At a minimum, the FSIS must devote additional resources to the inspection and testing of horses and horse meat to account for the administration of substances, including those listed in Exhibit 1, which may render horse meat unsafe for food.

The current NRP testing regime cannot ensure the safety of meat from horses specifically because, unlike most other animals inspected and tested by the FSIS for tissue residue violations, horses are not raised for human consumption. Horses who are *eventually* eaten are not raised in a regulated industry, and their exposure to drugs will not be monitored (if ever) until very shortly before they are sent to slaughter. During their existence as companion/work/sport horses, there are no controls in place to track their medical and drug histories, or to prevent their exposure to drugs and other substances that render them wholly unfit to become food. The horses' owners for most of their lives will have no reasonable expectation that the horses they are riding or training will end up as meat. Those owners and caretakers will have no need or desire in complying with FSIS restrictions on the amounts and types of drugs administered to horses who will become meat. Consequently, the horses will be given many of the substances listed in Exhibit 1 that are so dangerous that they do not have withdrawal times or tolerance levels but are prohibited for food animals, rendering horse meat unfit for food, injurious to health, and adulterated.

Specifically, the current NRP testing regime is inadequate to meet the particular challenges posed by horses because the two testing models were not designed to screen animals that are not raised to become food.[393] The first model, Scheduled Sampling, is of minimal use in

[393] *See* discussion of NRP testing *supra* Section V.A.2. That the NRP focus on drugs that *can* be given to horses at some point, as long as withdrawal times have been met, is further evidence that the current testing regime is inadequate to prevent adulterated horse meat from entering the food supply. Due to the important distinction between horses and animals actually raised to become food, a testing regime geared toward monitoring tissue residue violations in the latter is necessarily inadequate to meet the risks posed by the former. For horses, one of the biggest

(Footnote continued on next page)

screening random samples of horses for particular chemical residues because (1) the data upon which the annual Scheduled Sampling Plans are based is both outdated and collected too long after horses are treated with banned substances,[394] (2) the algorithm used to create the Scheduled Sampling Plans is outdated and inflexible,[395] and (3) the lack of data on chemical compounds that should be tested makes it likely that the FSIS will underestimate – and under-test – these compounds, which are commonly administered to horses.[396] Moreover, while random testing based on algorithms may be both efficient and precise when applied to a relatively uniform, known quantity of commercially raised food animals and production facilities, it is imprecise and

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(Footnoted continued from previous page)

problems is the administration of prohibited drugs, which may never show up under the current testing regimen.

[394] Data used to devise the annual Scheduled Sampling Plans comes from prior investigations of residue violations for each animal-compound combination and veterinary inventories completed during on-farm visits. *See* United States National Residue Program, *supra* Note 174, at vi. This means that data on horses is *at least* five years old. Moreover, even if the data was more recent, evidence collected on farm visits reveals little, if any information on the drugs administered to horses by the myriad of potential previous owners they had, who include *mostly non-farm situations*. Thus, the data both will not detect the inherent problems described in the Petition, and cannot be done at the proper source of potential exposures.

[395] According to the USDA Report on the FSIS' Microbiological and Residue Sampling Programs, the algorithm "has been unchanged for approximately ten years and contains variables . . . that may no longer be appropriate measures for prioritizing hazards" and "is a 'one size fits all' strategy that determines the number of samples collected, regardless of the product class/compound pairing, geographical or seasons trends." Report on the Food Safety and Inspection Service's Microbiological and Residue Sampling Programs, *supra* Note 189, p. 71.

[396] Because statistical evidence of violation rates for the administration of many of the Exhibit 1 compounds to horses is not available, the FSIS will use this absent, and therefore misleading, estimate of their violation rates if it decides to test for them. *See* United States National Residue Program, *supra* Note 174, at 21. The FSIS only tested horses for *11 of the 115* drugs listed in Exhibit 1 in 2006 and 2007, when horses were last slaughtered for human consumption. *See* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203; Exhibit 1. And even if the FSIS looks at data from FSIS tests of other food animals to help determine which drugs to test in horses, it only has test data for 2006 through 2009 (the year of the most recent published test data) on 68 of the 115 drugs listed in Exhibit 1. *See* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203; Exhibit 1; 2008 FSIS National Residue Program Data (USDA 2009) (attached hereto as Exh. 65); 2009 FSIS Residue Sample Results (USDA 2011) (attached hereto as Exh. 66). Given that the NRP views horses the same as they view animals raised for food from birth, it is likely that the FSIS will underestimate violation rates for these substances and, consequently, under-test them. *See generally* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203.

inefficient when applied to horses, for whom the number of owners, drugs, and drug combinations is nearly infinite.

Under this first testing model, horses whose tissue is tested may only be tested for a *single drug*.[397] Given the unreliable NRP algorithm; the nonuniform manner in how horses are raised, treated, and administered veterinary drugs; and the plethora of drugs listed in Exhibit 1 that are commonly administered to horses, it is likely that most horses contain violative residues of multiple drugs that, like those listed in Exhibit 1, are particularly dangerous. Yet even animals who are selected for a tissue residue test by the FSIS are often still not identified by the FSIS or reported to the FDA for enforcement. Further, when the FSIS tested horses under the 2006 and 2007 Scheduled Sampling Programs (before horse slaughter was effectively banned), it only tested horses for *11* of the 115 drugs listed in Exhibit 1, which are commonly administered to horses and pose danger to humans who consume meat from those horses.[398]

In contrast to the Scheduled Sampling Program, the FSIS' second testing model, the Inspector Generated Sampling Program, would be beneficial if applied properly to horses but is too expensive to be applied as needed. For this program, FSIS inspectors must collect tissue samples *every time* there is reason to believe that a violative residue is present, without exception.[399] This would apply to every American horse, given the reasons for conducting an in-plant test, which include evidence of suspect "production practice" and "herd history."[400] As described in the Petition, even a basic understanding of how most American horses who end up as meat are raised – especially knowledge of the information in Exhibit 1 and supporting

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[397] *See* FDA Directive 7371.006, Illegal Residues in Meat, Poultry, Seafood, and Other Animal Derived Foods (H.H.S. 2005), *supra* Note 101, at 18.

[398] *See* 2006 FSIS National Residue Program Data, *supra* Note 203; 2007 FSIS National Residue Program Data, *supra* Note 203; Exhibit 1. In 2006, the FSIS included horses in the Scheduled Sampling Program but did not test them for phenylbutazone, even though "musculoskeletal injuries are frequent in horses and are treated commonly with [phenylbutazone] to ameliorate the pain associated with these injuries." *Phenylbutazone Health Risks*, *supra* Note 106, at 1273.

[399] *See* FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program, (USDA 2007), *supra* Note 194, p. 11 (emphasis added).

[400] FSIS Directive 10,220.3, *supra* Note 206, p. 2.

declarations – is more than sufficient to raise suspicions that multiple violative residues, that would render meat adulterated, are present on a regular basis.[401] Similarly, a fundamental understanding of the history of certain types of horses, such as companion and race horses, for whom the use of anti-inflammatory drugs and steroids is well-known,[402] is more than sufficient to give reason to believe that violative residues would be found.[403]

Even this screening model, if done constantly and diligently, will not identify many problems. These in-plant screenings do not detect non-steroidal anti-inflammatory drugs such as flunixin and phenylbutazone. In order to perform that kind of assay, the FSIS inspectors would need to take further tissue samples for laboratory testing if they suspect the use of this category of drugs.[404] Yet these drugs are widely used for virtually all horses who go to slaughter.[405] Based on their "production practice" and "herd history," inspectors will need to perform tests to determine if these kinds of violative residues are present in a substantial percentage of horses.[406] Accordingly, faithful application of the Inspector Generated Sampling Program to horses would result in the expenditure of vastly more funds than Congress appropriates for the entire NRP, much less one testing model for application to a single species. But if the FSIS did not effectively apply the Inspector Generated Sampling Program to horses, it would be knowingly permitting the entry of adulterated horse meat into the food supply and the potential infliction of illness and possibly even death on consumers.

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[401] *See* FSIS Directive 10,800.1, *supra* Note 194, p. 11; FSIS Directive 10,220.3, *supra* Note 206, p. 2; Exhibit 1.

[402] *See Phenylbutazone Health Risks*, *supra* Note 106, pp. 1270-73. According to the authors of that article, of 18 race horses in a study who were sent for intended slaughter, all 18 were administered phenylbutazone, 6 of them within a month of slaughter. *Id*. at 1271. Over 90,000 race horses were slaughtered in the five years over which the authors examined data. *Id.*

[403] *See* FSIS Directive 10,800.1, *supra* Note 194, p. 11; FSIS Directive 10,220.3, *supra* Note 206, p. 2.

[404] *See* FSIS Directive 10,800.1, *supra* Note 194, p. 11.

[405] Wood Dec., Exh. 2 at ¶¶ 6-7; Larson Dec., Exh. 3 at ¶ 7; Pavlis Dec., Exh. 4 at ¶¶ 4-5; Parker Dec., Exh. 5 at ¶¶ 7-9.

[406] *See* FSIS Directive 10,220.3, *supra* Note 206, p. 2.

Slaughter establishments are similarly obliged under FSIS regulations to prevent, eliminate, and minimize food safety hazards, including the slaughter and sale of horse meat from horses (1) treated with prohibited veterinary drugs, (2) containing excessive amounts of drug residue, or (3) containing unsafe food additives.[407] And like FSIS, their current programs simply cannot provide any satisfactory level of protection. That these prohibited veterinary drugs and food additives are usually administered to horses before they enter a slaughter facility does not reduce the obligation of slaughter establishments.[408] If slaughter establishments do not develop and implement a Hazard Analysis and Critical Control Points ("HACCP") plan that accounts for these known food safety hazards, which at the very least would require them to refuse groups of horses for slaughter based on their "herd history," their horse meat products should be deemed adulterated.[409] In other words, just like FSIS, without significant additional resources and a major overhaul of their testing processes, there is simply no way slaughterhouses can be expected to detect all the hidden problems with horse meat described in the Petition, and so it all must be deemed adulterated. As currently set up, the HACCP program is born to fail, for the same reasons that are stated in the Petition in connection with FSIS' obligations to detect these substances and eliminate adulterated meat from the marketplace.

6. Adulterated Horse Meat Can Be Excluded from the Food Supply Only if Complete Treatment Histories Are Kept for All Horses Slaughtered for Human Consumption.

Just because a horse's tissue residue test results for a given drug are negative, that does not mean that the horse has never been administered that drug or even that the tissue does not contain the drug. Even the most thorough testing regime is unlikely to uncover which horses have been administered substances that must never be used "in horses intended for human consumption"[410] and that render the horses' meat adulterated. Consequently, implementing and

[407] *See* 9 C.F.R. § 417.2(a)(1), (3)(v), (ix), (b)(i), (c)(1)-(4).

[408] *See* 9 C.F.R. § 417.2(c).

[409] *See* 9 C.F.R. § 417.2(e).

[410] *See, e.g.*, 21 C.F.R. § 520.1720a (declaring that tablets and boluses of phenylbutazone cannot be used "in horses intended for human consumption").

rigorously enforcing a "passport system" that requires horse owners to keep a verifiable lifetime medical treatment history for each horse is the only way the FSIS can prevent the entry of adulterated horse meat into the nation's food supply.

Individuals who administer banned substances to their horses are often unaware that their horses will become food, and the FSIS is unlikely to detect and prevent the administration of these banned substances, especially since these individuals are largely unknown and effectively unidentifiable. Moreover, the FSIS will be unable to determine the presence of the banned substance in the horse and its flesh when the drug remains in the horse but is undetectable via residue tests – or when, as demonstrated above, the drug is never even in the list of FSIS' tested substances. This is especially true given the relatively wide dispersal of the administration of banned substances to horses – at stables and farms, in competitions and at racetracks across the country[411] – and the passage of time between a horse's treatment with banned substances and slaughter. And this would be true *even if* the FSIS faithfully applied the Inspector Generated Sampling Program to horses, as discussed in the previous Section.

The primary types of evidence gathered by FSIS inspectors engaged in ante-mortem and post-mortem inspections – observations of horses just before slaughter, tissue from horses just before slaughter, and observations of and tissues from horses carcasses after slaughter – do not address the time periods in which horses have been administered prohibited substances.[412] Without a drug and dangerous substance exposure list that is kept for horses' entire lives, and that can be reviewed and scrutinized by FSIS inspectors and slaughterhouse personnel at the time of their slaughter, there is no possible way to determine the likely inevitable conclusion – that American horses, and their meat, are "adulterated" and should not be allowed to proceed to slaughter. Certainly the current practice, which provides only for a limited determination of drugs and prohibited substances used on horses in their last few days or weeks, cannot come

[411] Wood Dec., Exh. 2 at ¶¶ 6-7; Larson Dec., Exh. 3 at ¶ 7; Pavlis Dec., Exh. 4 at ¶¶ 4-5; Parker Dec., Exh. 5 at ¶¶ 7-9.

[412] *See* FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, *supra* Note 190; FSIS Directive 6100.2, Post-Mortem Livestock Inspection, *supra* Note 192.

close to telling the full story the FSIS needs to ensure the public is safe when it eats the flesh of those horses. In order to protect the public and the market and the food supply, the FSIS needs to know about *all* the drugs and drug-containing products administered to the horse *before* the horse was sent off to be slaughtered.

Comprehensive medical records from birth are the only way to ascertain drug exposures, and given the various purposes for which humans own horses before they enter the slaughter pipeline, those records are unlikely to exist and virtually impossible to locate. Put differently, the evidence currently collected by FSIS inspectors does not and cannot provide the necessary drug history of an animal such as a horse who has had multiple owners, especially where the animals were never contemplated as meat and those prior owners are unknown and effectively unidentifiable. As the necessary data to ensure public safety is simply unascertainable when horses are the species being slaughtered, FSIS inspection procedures are unable to capture the necessary information. Without comprehensive treatment records, adulterated horse meat will enter the food supply and cause harm, disease, or even death to unsuspecting consumers.

C. The Treatment of Horses Going to Slaughter and the Processing of the Horses Increases the Chance the Horse Meat is Adulterated and Unfit for Food

As documented in Sections IV.E and IV.F above, the procedures of horse transport and slaughter, for the horses and the communities involved, also brings into question the unhealthy and unsafe nature of horse meat. Because of the documented suffering of horses shipped to slaughter, and the treatment of the horses while they are at the slaughter house, the potential for the spread of bacterial diseases, blood-borne infecting agents, and other health hazards is high.[413] Because of the ingestion by the horses of a long list of dangerous, often toxic, substances, the entire environment around a horse slaughter plant is in danger. In addition to the unpredictable and unidentifiable presence of the substances on Exhibit 1 in horse meat, the potential that they

[413] *See, e.g.*, Larson Dec., Exh. 3, ¶¶ 12-13, 15-16, 18-19, 25.

are also sick presents a further reason for the FSIS to seriously consider the use of American horses for meat at any juncture.[414]

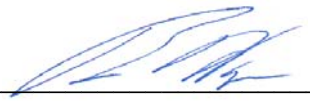
VII. CONCLUSION

American horses are cared for, used and treated as companions, as competitors, as work partners. Their owners, caregivers and veterinarians administer a wide array of drugs and other substances to keep the horses healthy, strong, and productive. Most, if not all, of these substances are either prohibited by federal law for use in animals who will become meat, or are potentially dangerous to a significant percentage of humans who eat these substances. Not only do Americans not eat horses, their horses are not meant to be meat, and any American horse that becomes meat is a danger to the consuming public. It is imperative that the FSIS eliminate the threat created by the slaughter of American horses for food, in order to prevent the spread of unsafe meat in America and throughout the world.

VIII. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners which are unfavorable to the Petition.

Dated: April 6, 2012



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[414] *See* Wood Dec., Exh. 2 at ¶ 9.

CITATIONS, BIBLIOGRAPHY, AND EXHIBIT LIST

CASES

STATUTES

REGULATIONS

REGULATIONS (*Continued*)

EXHIBIT LIST

Exh.#	Document
1.	Banned and Dangerous Substances Commonly Given to Horses Sent to Slaughter
2.	Declaration of Hilary Wood
3.	Declaration of Peggy W. Larson, DVM, MS, JD
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