August 22, 2012

**VIA FEDERAL EXPRESS**

The Honorable Thomas J. Vilsack
Secretary of Agriculture
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington DC 20250

Dear Secretary Vilsack,

Please accept this letter, on behalf of Front Range Equine Rescue ("FRER"), as a response to the inaccurate and misleading claims made in the July 31, 2012 "Urgent Petition" submitted by Sue Wallis on behalf of the International Equine Business Association (the "Petition"). Wallis represents the interests of a small group of individuals and business interests who seek to profit by slaughtering American horses for human consumption, while ignoring the extensive societal and individual dangers of horse slaughter. If American horses are again slaughtered for meat, the costs of Wallis' profit centers will be borne by the federal agency budgets that will need to adjust for the exceptional burdens inherent in horse slaughter regulation, as well as by taxpayers. It is also well-documented that American horse slaughterhouses have created an environmental and community nightmare for local interests—homeowners who live near slaughterhouses must deal with the pervasive foul odor, environmental degradation, and other negative externalities. Finally, the production of horse meat from American horses is a toxic business, because virtually all horse meat from American horses is adulterated, unfit for human consumption, and dangerous. Wallis does not represent (and ignores) the interests of the large percentage of Americans, who have confirmed their strong objection to American horse slaughter; and she avoids discussion of the slaughter process for horses, which is especially cruel and terrifying. Ignoring the long string of perils related to horse slaughter, Ms. Wallis demonstrates an utter lack of interest in the truth.

The Petition contains numerous demonstrably false claims, which I correct below, along with FRER's overall response.

**No Horse Processing Facilities Are Even Close to Ready to Operate.**

The Petition falsely claims that "[s]everal horse processing facilities are ready to offer horse owners a fair price for the animals . . . or could be within days." As FSIS is well aware, currently there is not even *one* authorized horse slaughter facility in America, and the authorization process takes some time. This is one of many cases where the Petition says one thing, and the *exact opposite* is true—leading to a question of credibility with respect to every statement made in the Petition. The fact is, there are *no* horse processing facilities ready to pay horse owners for horses that they may never be able to slaughter.

There are only two entities that have even *applied* for inspection with FSIS this year. Both face significant, if not insurmountable, obstacles. Wallis' own Unified Equine, LLC, wants FSIS to let it operate a horse slaughter establishment in Rockville, Missouri.[1] Yet, Unified Equine does not even own the plant that it seeks to open.[2] Instead, this former beef processing plant is "mired in a heap of ownership and legal troubles."[3] Specifically, its owner faces two felony counts for theft related to his operation of the plant, and title to the plant is tied up with liens related to the owner's fraudulent conduct.[4] Wallis may soon abandon efforts to establish a horse slaughter plant in Rockville, just as she did earlier in 2012 in Mountain Grove, Missouri.[5] Even if she does not, this information should give FSIS serious pause before even considering Unified Equine's application. (FRER can provide FSIS with additional relevant documentation relating to the legal problems facing the Rockville plant, upon FSIS' request.)

The other entity, Valley Meat Co., seeks to convert its Roswell, New Mexico cattle slaughter establishment into a horse slaughter establishment,[6] but it too faces legal problems. For over two years (from at least January 2010 until May 2012), while slaughtering cattle, Valley Meat ignored New Mexico laws on solid waste disposal. Despite repeated warnings from the New Mexico Environment Department's Solid Waste Bureau, Valley Meat dumped animal remains into piles outside its establishment, leaving them to rot.[7] Some of the piles of rotting flesh reached 15 feet in height, threatening the environment and public health.[8] For its consistent, flagrant violation of state law, Valley Meat was recently assessed an $86,400 fine, with the prospect of significant additional fines in the future.[9] Valley Meat's owner had been

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[1] Unified Equine, LLC Application for Federal Inspection (attached hereto as Exhibit 1).

[2] Donald Bradley, *No progress on horse slaughter plant in Rockville, Mo.*, THE KANSAS CITY STAR (July 22, 2012), http://www.kansascity.com/2012/07/06/3718025/no-progress-yet-on-proposed-rockville.html.

[3] *Id.*

[4] *Id.*; Josh Nelson, *No progress in opening Rockville horse slaughter plant*, THE SPRINGFIELD NEWS-LEADER (July 24, 2012), http://www.news-leader.com/article/20120724/NEWS01/307240024/Horse-slaughter-plant-Rockville-Sue-Wallis.

[5] Stephen Deere, *Horse slaughter plans for Missouri are on hold*, ST. LOUIS POST-DISPATCH (Aug. 10, 2012), http://www.stltoday.com/news/local/metro/horse-slaughter-plans-for-missouri-are-on-hold/article_ee9019c8-f312-5516-a402-45ccb7ee0d1c.html.

[6] Valley Meat Co., LLC Application for Federal Inspection (attached hereto as Exhibit 2).

[7] *New Mexico Environment Department v. Valley Meat Company, LLC*, No. SWB 12-16 (CO) and August 2, 2012 Solid Waste Bureau Letter to Ricardo De Los Santos (attached hereto as Exhibit 3).

[8] *Id.*

[9] *Id.*

complaining about financial concerns even before this recent fine.[10] Now he is either planning to resume slaughtering cattle, or to wait for FSIS' decision on his application.[11] Regardless, given a tenuous financial situation combined with Valley Meat's long-term violations of environmental laws, FSIS should be very concerned about approving a horse slaughter operation at this site.

Even if these two applicants did not face their own legal problems, they still will not be able to slaughter horses until FSIS approves their application and they pass inspection. And because horse slaughter has not occurred in the United States since 2007, FSIS must update its regulations and procedures before approving applications and inspecting prospective horse slaughter establishments. This process will take "significant time,"[12] and it is unknown when, or if, FSIS will be ready to begin inspections.

FSIS also has before it the Petition for Rulemaking filed by FRER and The Humane Society of the United States, on April 9, 2012, Docket No. 12-14, which raises significant and serious questions about the dangers of horse meat and horse slaughter, for consumers, neighbors of horse slaughter plants, and the environment. Before it grants any applications for horse slaughter, the agency should carefully evaluate and issue a decision on that Petition.

Additionally, most states and localities require slaughter establishments to comply with numerous laws and regulations, from zoning and licensing requirements to environmental and public health laws. It is unclear whether these two establishments, or any other potential applicants, are prepared to satisfy state and local regulatory requirements. In order to protect the public and the sanctity of the federal regulation system, FSIS should ensure that any applicants for new horse slaughter are in full compliance.

In short, in contrast with Ms. Wallis' purported knowledge of things that only FSIS could know, it is clear that no would-be horse slaughter establishment is close to ready to begin operations.

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[10] *See e.g.*, *N.M. meat plant owner defense horse slaughter*, AZCentral (Apr. 14, 2012), http://www.azcentral.com/news/articles/2012/04/14/20120414PNI0414-wir-new-mexico-horse-slaughter-meat-plant.html.

[11] Rene Romo, *Meat Plant Fined for "Rotting Waste,"* ALBUQUERQUE JOURNAL (Aug. 17, 2012), http://www.abqjournal.com/main/2012/08/17/news/meat-plant-fined-for-rotting-waste.html.

[12] Milan Simonich, Family gives up on horse-slaughter plant in New Mexico, Las Cruces-Sun News (Aug. 14, 2012), http://www.lcsun-news.com/las_cruces-news/ci_21310956/family-gives-up-horse-slaughter-plant-new-mexico.

**Neither Domestic Nor Foreign Markets Are Ready to Accept Meat from American Horses.**

The Petition also falsely claims that "[m]arkets for the product are ready to accept it domestically and internationally if the meat is USDA-inspected exactly as it was in 2007."[13] This claim is absurd, both because there is virtually *no* domestic demand for horse meat, and because meat from American horses does not meet international food safety standards and soon will be barred from export to the European Union ("EU"), where much of it is presently shipped (after American horses are slaughtered in Canada or Mexico).

First, "Americans do not eat horse meat. . . ."[14] While some Americans ate horses in decades past, consumption has dropped off to almost nothing in the past thirty or forty years. At this point, horse meat is almost never eaten in America. Instead, Americans treat their horses as companions, sources of recreation, and tools of labor, and American horses are much more like dogs and cats than cows, pigs, and chickens. Consequently, a "commercial market for horse meat as food has never emerged in the USA."[15]

Nor do Americans want other Americans slaughtering their horses for human food. A January 2012 poll revealed that eighty per cent of Americans are strongly opposed to horse slaughter.[16] 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.[17] Americans' treatment of horses,

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[13] USDA's 2007 standards and procedures are outdated and inadequate. *See* Petition To Create Rules and Regulations Governing the Sale, Transport and Processing of Horses and Horse Meat Intended for Human Consumption, FDA Docket Number FDA-2012-P-0299-0001/CP, http://www.frontrangeequinerescue.org/documents/petition.fda.slaughter.pdf (explaining that horse meat from virtually all American horses is adulterated and unsafe for human consumption under current federal law and FDA regulations); Petition To Create Rules and Regulations Governing the Sale, Transport and Processing of Horses and Horse Meat Intended for Human Consumption, FSIS Docket Number FSIS-2012-P-12-04, http://www.fsis.usda.gov/PDF/Petition_SchiffHardin_040612.pdf (explaining that horse meat from virtually all American horses is adulterated and unsafe for human consumption under current federal law and FSIS regulations).

[14] *See Cavel Int'l., Inc. v. Madigan*, 500 F.3d 545, 545 (7th Cir. 2007).

[15] *See* 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), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2034431/.

[16] http://www.prnewswire.com/news-releases/aspca-research-confirms-americans-strongly-oppose-slaughter-of-horses-for-human-consumption-138494089.html ("*ASPCA Survey*"); *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), http://www.humanesociety.org/news/press_releases/2011/11/usda_threatened_02032012.html.

[17] *ASPCA Survey*, *supra* Note 16.

the historical role of horses,[18] horses' place in American culture,[19] and the cruelty connected with horse slaughter make it a practice that has never received much support.[20]

Second, the EU, the primary export market for American horse meat, has recently implemented its own heightened food safety requirements for horse meat. While most of these requirements already apply to meat from American horses, the requirements soon to apply to American horses will prohibit the importation of horse meat from horses who are not accompanied by lifetime treatment records.[21] Because virtually all American horses currently lack these records, and because it is virtually impossible to create or obtain such records, American horses will be ineligible for sale to any EU member-nation.

In order to protect public health and avoid environmental contamination, the European Parliament and the Council of the EU adopted a regulation on the importation of food-producing animals and their meat.[22] This regulation bans horse meat from horses that have been treated with any drug on a list of identified prohibited substances. Many of the drugs on the list are regularly administered to American horses.[23] The regulation also establishes maximum residue limits of pharmacologically active substances permitted in food-producing animals, and outlines procedures for testing those animals to ensure compliance with the regulation.[24] These rules apply to all horses intended for human consumption, or horse meat from such horses, sent from the U.S. and destined for the European market. At this point, the U.S. is nowhere close to having a system in place to comply with these requirements.

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[18] 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.

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

[20] *See, e.g.*, Declaration of Peggy W. Larson ("Larson Dec."), ¶¶ 11-21 (attached hereto as Exhibit 4).

[21] *Residues of Veterinary Products, Third Countries*, Europa Website, at 6 ("*Residues of Veterinary Products*") (attached hereto as Exhibit 5).

[22] Council Regulation 470/2009, 2009 O.J. (L 152) (EC).

[23] *See* Declaration of Hilary Wood ("Wood Dec."), ¶¶ 6-7 (attached hereto as Exhibit 6); Larson Dec., Exh. 4, ¶ 7; Declaration of Joanne Pavlis ("Pavlis Dec."), ¶¶ 4-5 (attached hereto as Exhibit 7); Declaration of Randy Parker, D.V.M. ("Parker Dec."), ¶¶ 7-9 (attached hereto as Exhibit 8).

[24] *Residues of Veterinary Products*, Exh. 5 at 11.

In order to comply with the EU's requirements, the U.S. must establish or implement the following measures:

First, the U.S. must establish an identification and verification system for *all* horses intended for food production.[25]

Second, horses given anabolic steroids for growth purposes, and other prohibited substances, must be identified and segregated from horses who will be exported to Europe for human consumption.[26] Unless the United States establishes a "split system" to separate horses who have been treated with those substances from those destined for export to Europe, meat from American horses cannot legally enter the EU or be sold there.[27] No such system currently exists, and because all horses are commingled throughout their lives, it is unlikely that one can ever be established.

Third, only horses with known medical treatment histories may be slaughtered and exported to Europe as consumer-grade meat.[28] All horses must be accompanied by an identification document, which the Commission calls a "passport," on which each horse's owner must record *all* veterinary medical treatments received by each horse.[29] While exporters from non-EU nations currently need only guarantee that their horses have not been administered a banned substance within six months of sale, by July 2013, all horses meant for human consumption in Europe must be accompanied by a passport.[30]

Fourth, the federal government must guarantee that each horse slaughtered for human consumption has never received any banned substances, and is free from restricted substances for the required withdrawal periods.[31]

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.[32]

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[25] *Id*. at 6.

[26] *Id*.

[27] Council Directive 96/22/EC, art. 11 (2), 1996 O.J. (L 125) 3, 7 (EC); *id.*

[28] *Residues of Veterinary Products,* Exh. 5 at 6.

[29] *Id*.

[30] European Parliament Parliamentary Questions, Answer given by Mr. Dalli on behalf of the Commission (29 November 2010), http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2010-9125&language=EN ("*European Parliament Parliamentary Questions*").

[31] *Residues of Veterinary Products,* Exh. 5 at 6.

The U.S. regulatory regime cannot satisfy these requirements because:

First, the U.S is unlikely to establish a mandatory identification and verification system for horses. As there is no mandatory identification system for animals who are raised to become food, such as cattle, it is unclear how the U.S. would implement such a system for horses, especially when most horse owners do not know or care about the applicability of food safety requirements to their horses.[33]

Second, regulators will not be able to identify and segregate horses who have ever been administered anabolic steroids and similar banned substances unless the U.S. implements a passport system.

Third, a functioning passport system for American horses is unfathomable. American horse owners do not view themselves as "producers" of meat or want their horses to become food. Consequently, they will not know about the lifetime medical records requirement or care to adhere to it. Because it is unrealistic to think that Congress will require American horse owners to keep lifetime medical records for their horses so they can be eligible for slaughter and human consumption at a European dinner table, such a system would have to be optional. But because the only consequence for failure to keep these records would be the ineligibility of their horses to become food for Europeans, few American horse owners will implement a passport system. And this all assumes that Congress would establish such a system, which, based on the unpopularity of horse slaughter, is not at all likely.

Fourth, as FSIS does not currently require horse owners to maintain medical records, guarantee the origin of their horses, or take responsibility for the accuracy or authenticity of the sworn statements provided to Mexican and Canadian purchasers of American horses, it is unclear how or whether it will provide these guarantees for horses and horse meat destined for Europe.[34]

Fifth, it is impossible for U.S. inspectors to ensure that horse owners are adhering to EU regulations on the use of veterinary products and banned substances because American horse owners do not view themselves as "producers," do not raise horses for food in predictable settings like farmers raise cattle, and will not submit to inspections meant for producers of food when they have no intention of their horses becoming food.

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[32] *Id.*

[33] *See* USDA Office of the Inspector General, Audit Report 24601-08-KC, FSIS National Residue Program for Cattle ("*OIG Report*"), p. 26-27 (2010), http://www.usda.gov/oig/webdocs/24601-08-KC.pdf.

[34] 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, at 15 ("*Canada Report 1*"); 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, at 7 ("*Mexico Report*").

American suppliers do not and cannot meet the treatment, identification, and inspection requirements established by the EU. Consequently, the world's largest market for horse meat will not accept meat from American horses.

**Drug Residue Testing Is Inadequate to Ensure that a Horse Has Never Been Administered a Banned Substance.**

The Petition claims that drug residue testing can "establish the eligibility of every horse for processing. . . ." This is categorically untrue.

Under the current unregulated system through which horse meat is produced from American horses, "it is not possible to know for sure" whether a particular horse's flesh is adulterated.[35] Neither the modern, high-efficiency methods of FSIS' National Residue Program, nor the most thorough residue testing regime imaginable, is likely to uncover which horses have been administered substances that must never be used "in horses intended for human consumption"[36]—especially since the undisputed evidence is that *virtually every horse* fits into this category. Consequently, implementing and rigorously enforcing a "passport system" that requires horse owners to keep a verifiable lifetime medical treatment history for each horse is the only way FSIS can prevent the entry of adulterated horse meat into the nation's food supply. As explained above, the U.S. will soon have to implement such a system for the EU to accept meat from American horses.

Complete treatment records for individual animals may be necessary even where the animals are regulated and their producer is specifically raising them to become food. For example, the FDA recently cited a veal producer for offering a calf for slaughter that was adulterated due to the presence of a banned substance in the animal's flesh and because the producer held its animals "under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply."[37] FSIS analysis of tissue samples collected from the producer's calves revealed the presence of residues of florenfenicol, a substance that is completely banned for use in calves to be processed for veal.[38] The producer's failure to keep track of the substances it administered to particular animals—its failure to "maintain complete treatment records"—led the FDA to conclude that the conditions

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[35] *See* Compliance Guide for Residue Prevention 2012, http://www.fsis.usda.gov/PDF/Residue_Prevention_Compliance_Guide_042512.pdf, at 5.

[36] *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").

[37] *See* Snellman Farms 6/1/12, Department of Health and Human Services Warning Letter CIN-12-302058-21 (attached here to as Exhibit 9). This warning letter is just one of over thirty warning letters issued by FDA in 2012, which cite animal producers for selling adulterated food based on their failure to maintain complete medical records.

[38] *Id*.

under which the producer kept its animals were such that meat from the animals was adulterated because it was "injurious to health" under 21 U.S.C. § 342(a)(4).[39]

While residue testing helped the FDA discover that the animal's flesh was adulterated, the finding of adulteration was not solely based on the positive residue test. Instead, the FDA independently deemed the producer's animals adulterated because the producer "failed to maintain complete treatment records."[40] The factual predicate for this finding of adulteration—conditions "whereby [food from the animal] may have been rendered injurious to health"—is unavoidable for unregulated animals such as American horses, given the way their owners raise them (not to be food), treat them (not as potential food), and think about them (as many different things, but not food).

Accordingly, the maintenance of complete treatment records to avoid adulteration is even more necessary for unregulated animals like horses. Individuals who administer banned substances to their horses are often unaware that they will become food, and FSIS is unlikely to detect and prevent the administration of these banned substances, especially since these individuals are largely unknown and effectively unidentifiable. Moreover, FSIS is very likely to miss dangerous drugs in horse meat. The agency may not detect dangers because it does not test all animals, and has never tested for more than a few of the many drugs given to horses. Additionally, 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. This is especially true given the relatively widespread administration of banned substances to horses—at stables and farms, in competitions and at racetracks across the country,[41] and the transfers of ownership after a horse's treatment with banned substances and before the horse's slaughter. And this would be true *even if* FSIS steadfastly applied National Residue Program testing to horses. That FSIS will lack the resources to test every horse for violative residues is further evidence of the need to track the treatment histories of all horses slaughtered for human consumption.

Without a drug and dangerous substance exposure list that is kept for horses' entire lives, which can be reviewed and scrutinized by FSIS inspectors and slaughterhouse personnel at the time of their slaughter, there is no possible way to refute the conclusion that meat from American horses is "adulterated" and *no* American horse should be slaughtered for food.[42] Certainly the

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[39] *Id.*

[40] *Id.*

[41] Wood Dec., Exh. 6 at ¶¶ 6-7; Larson Dec., Exh. 4 at ¶ 7; Pavlis Dec., Exh. 7 at ¶¶ 4-5; Parker Dec., Exh. 8 at ¶¶ 7-9.

[42] This conclusion is further compelled by a recent FDA warning letter, which cited an Ohio farm for selling for slaughter an adulterated horse. Not only was this horse adulterated because its flesh contained violative residues of banned substances, but it was also adulterated because it was held in inadequate conditions, which made it likely that its flesh would be adulterated.

current practice, which would provide only for a limited determination of drugs and prohibited substances used on horses in their last few days or weeks, cannot come close to telling the full story FSIS needs to ensure the public is safe when it eats the flesh of American horses. In order to protect the public, the market, and the food supply, FSIS needs to know about *all* of the drugs and drug-containing products administered to a horse *before* the horse is 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 Americans own horses before these horses enter the slaughter pipeline, those records are unlikely to exist and would be 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 owners never considered their animal to be meat and those prior owners are unknown and unidentifiable. As the necessary data to ensure public safety is simply unascertainable when horses are the species being slaughtered, the National Residue Program is 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.

**Due to the Unique Temperament of Horses, Horse Slaughter is Inherently Inhumane, Cruel, and Barbaric.**

The Petition's description of horse slaughter as a "humane option for horses" is Orwellian. Not even proponents of horse slaughter can believe that it is humane to shoot a horse multiple times with a captive bolt pistol while she frantically attempts to escape the "stun box." Yet, this is the experience of the average horse sent to slaughter, which is only the last act of cruelty after the extended mistreatment of horses during their journey to the slaughterhouse and at the slaughterhouse but before slaughter. Accurately described, horse slaughter is brutal and inhumane.

From their acquisition at livestock auctions to their arrival at the slaughterhouse, horses destined for human consumption are subject to mistreatment and cruelty.[43] Transportation to the slaughterhouse is often long and grueling, as horses are crammed into trucks that do not accommodate their physical requirements and unique temperaments.[44] The lack of proper food and water in already weakened horses can lead to further injuries and death during extended

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Specifically, the owner of the farm failed to obtain knowledge of the horse's medical treatment history. For more on this warning letter, see the text accompanying Notes 68-71.

[43] *See* Larson Dec., Exh. 4, ¶¶ 12-13, 15-16, 18-19, 25.

[44] Larson Dec., Exh. 4, ¶¶ 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."), http://jas.fass.org/content/77/11/2925.

transport. Some horses arrive at slaughterhouses with their backs broken or with other serious injuries.[45]

Poor conditions during the transportation of horses result in slaughter facilities filled with frightened, food- and water-deprived, sick and injured horses.[46] At slaughter facilities, horses are often subject to appalling abuse before and during their slaughter.[47] Many horses are not given hay or water in overnight holding pens.[48] And many of the horses in holding pens are "downers"— too sick or injured to stand up and walk, some of whom may be dragged or pushed into the pen.[49] Some of these ill, diseased, and injured horses would be unfit for food under the Federal Meat Inspection Act and Federal Food, Drug, and Cosmetic Act, and should not be slaughtered for human consumption.[50]

Because horses frighten more easily than other animals, they are unsuited to be processed at a slaughter plant.[51] As horses are more sensitive to odors than cows, the scent of blood that necessarily exists in the slaughter facility exacerbates their fright.[52] Some horses slip and fall in

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[45] *See* Larson Dec., Exh. 4, ¶ 13; *see also* 151 CONG. REC. H4247 (horses are "transported in excess of 1,000 miles in the most inhumane conditions perceived").

[46] *See* Larson Dec., Exh. 4, ¶¶ 16-18.

[47] *See* Larson Dec., Exh. 4, ¶¶ 15, 18-19.

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

[49] Larson Dec., Exh. 4, ¶ 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."), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC291172/.

[50] *See* 21. U.S.C. § 342(a)(4) (establishing the food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. . . ."; 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").

[51] *See* Larson Dec., Exh. 4, ¶¶ 18, 25.

[52] *See* Larson Dec., Exh. 4, ¶ 18.

the stun box.[53] Due to their keen perception and subsequent fear, horses are more likely than other animals to injure themselves trying to escape the slaughter plant.[54]

Under federal law, horses must be rendered unconscious prior to slaughter,[55] 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.[56] According to a recent report, almost half of the horses going to slaughter had to be stunned more than once.[57] 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.[58] The mistreatment is an inevitable occurrence anytime horses are slaughtered, as documented most recently in Canada.[59] The examples cited above, which are only those that were discovered and occurred in a small sampling of plants, speak volumes for the absolute terror that horses experience at slaughterhouses, and the danger to them and to the public in processing them for meat.

Numerous words describe the horse slaughter process. "Humane" does not.

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[53] *See Pasture to Plate*, *supra* Note 48, at 4.

[54] *Id.* at 5.

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

[56] *See* 151 CONG. REC. S10,220 (daily ed. June 8, 2005) ("horses sometimes remain conscious throughout the slaughter process"); *see also* Larson Dec., Exh. 4 at ¶ 18.

[57] *Pasture to Plate*, *supra* Note 48, at 4.

[58] *See*, *e.g.*, USDA, Food Safety & Inspection Service, Noncompliance Record No. 0019-2005-8243 (Apr. 13, 2005); *see also, e.g.*, Noncompliance Record Nos. 00 18-2005-8243 (Apr. 4, 2005) ("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) ("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) ("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), http://www.kaufmanzoning.net/nov24/ pressrelease.pdf; *see also* Mary Nash's Horse Meat Website, http://www.kaufmanzoning.net/foia.htm (making available for download USDA documents describing and depicting regulatory violations, mistreatment, and cruelty).

[59] *See generally Pasture to Plate*, *supra* Note 48.

**Canada's Equine Identification and Tracing System Is Unreliable and Susceptible to Fraud.**

The Petition recommends reliance on the equine identification and tracing system used in Canada, claiming that it is "tested and proven." Canada has indeed "tested" this system, and the system has failed those tests. The evidence produced by these tests has also "proven," repeatedly, that the system is unsuccessful and undependable.

As revealed by European Commission (the "EC") Audit Reports and recent evidence of widespread fraud regarding representations as to the drug history of American horses, certifications that horses have not been exposed to banned and dangerous substances within a short period before slaughter are not credible, and any reliance on those certifications seems to be folly. Moreover, the entire notion of certifying that a horse's meat is untainted is dubious in light of the fact that virtually all American horses are administered banned and dangerous substances. For these horses, the presence of violative drug residues is irrelevant, as their flesh is *adulterated regardless of the results of a residue test*. Consequently, the recommendation that horse slaughter establishments require documentation from producers that animals are "Drug Residue Free" is unworkable, and even if certifications were reliable, this would do nothing about the widespread administration to horses of banned substances.

The EC recently published the results of audits undertaken in order to evaluate Canadian and Mexican compliance with EU regulations, which restrict imports based on the prior exposure of the horses to a variety of banned and dangerous substances.[60] These audits revealed that both countries' controls over the production of horse meat from American horses are inadequate to protect consumers.[61] 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 not been administered banned veterinary drugs and other potentially harmful drugs and substances within six months of sale, without providing medical records or any kind of formal guarantee.[62] Often these individuals have not even owned the horses for the period of time to which they are attesting. Moreover, even if this system was accurate, it is irrelevant under American law that a horse has not been administered a banned substance for six months, as the administration to a horse of a banned substance on a single

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[60] Council Regulation 470/2009, 2009 O.J. (L 152) (EC); Council Directive 96/22/EC, art. 11 (2), 1996 O.J. (L 125) 3, 7 (EC); Council Directive 96/23/EC, art. 29, 30, 1996 O.J. (L 125/10).

[61] *Canada Report 1*, *supra* Note 34 at 12-16; *Mexico Report*, *supra* Note 34 at 6-9; 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*") (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.* Notably, of the 30,000 horses slaughtered in Canada in 2011, 85% were from the U.S., and 90% of slaughtered horses were exported. *Id.*

[62] *See generally Canada Report 1*, *supra* Note 34; Mexico Report, *supra* Note 34.

occasion, regardless of how much time has elapsed, *automatically* renders that horse's flesh adulterated, and consequently renders sale of the horse's meat illegal under American, Canadian and EU law. 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 foreign consumers. There is no reason to think that this system would work any differently if American horse meat is sold to American consumers.

The EU currently requires a certification system for American horses whose meat is sold in Europe. This system does not work. Under this system, Americans who sell horses for slaughter to Canadian or Mexican companies must 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.[63] 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 solely for the purpose of selling the horse for slaughter. While that recent seller issues an affidavit to accompany the horse in which he declares that the horse has not been administered any banned substances, those statements are always made without knowledge of their accuracy.[64] 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 proof emerged that the horses had ever been administered any of the prohibited substances.

Even if the final purchasers or sellers are able to provide an accurate statement regarding their knowledge of the horses' exposure to certain drugs in the limited time they have owned them, they cannot possibly know what drugs the horses were given over the course of their lives. The potential is clear for both inadvertence and fraud that will lead to unsafe food being consumed by purchasers due to reliance on certifications. Since many of the drugs and substances commonly administered to horses render the horses' meat *permanently* unfit for human consumption, the system of sending American horses for slaughter, in its present form, is hopelessly flawed and dangerous.

Additionally, Americans who buy and sell horses for slaughter and certify their flesh as safe often provide fraudulent information. At one horse export market selling horses to be exported to and slaughtered in Canada, blank declarations (besides signatures) were randomly connected with horses sold for slaughter; there was no actual reference to the specific horse, and

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[63] 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. After July 2013, countries that export horses whose meat is sold in the EU market must adopt a similar system. *See Residues of Veterinary Products*, Exh. 5; *European Parliament Parliamentary Questions*, *supra* Note 30.

[64] *Canada Report 1*, *supra* Note 34 at 15; Mexico Report, *supra* Note 34 at 7.

no accurate information about that horse was passed along.[65] These declarations purportedly certified that the horses they accompanied had never been administered any prohibited substances when, in reality, they were prepared *without regard to their accuracy or the identity of the horse*.[66] Other individuals have witnessed auction houses complete the declarations for owners, even though the auction houses obviously knew nothing about the animals.[67] Given the lack of any viable controls on the quality of meat from American horses and on certifications that this meat is not adulterated, the recommendation that meat be treated as safe when certified safe, while useful when applied to regulated food animals, does not apply to horses.

An American horse that was sold and slaughtered in Canada epitomizes the folly of relying on Canada's equine identification and tracing system. The FDA recently issued a warning letter to "Patron Farms, LLC" in Canfield, Ohio for offering for sale for slaughter a horse that was adulterated.[68] Specifically, the horse was adulterated because its flesh contained two banned substances—phenylbutazone and clenbuterol—and it was held in conditions "so inadequate that medicated animals bearing potentially harmful drug residues [we]re likely to enter the food supply."[69] In this warning letter, the FDA suggested that the dealer "implement[] a system to determine from the source of the animals whether the animal[] has been medicated and with what drug(s). . . ."[70] This suggestion should be a requirement for all horse dealers, but it is difficult, if not impossible, for this type of system to be established without the federal

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[65] *See Investigation on horse meat entering Europe from America*, ITALIAN HORSE PROTECTION ASSOCIATION, http://www.horseprotection.it/dett_articolo.asp?id_a=379; *see also* Photographs of the New Holland Auction, http://www.horseprotection.it/docs/eid/album/index.html.

[66] *See Investigation on horse meat entering Europe from America*, ITALIAN HORSE PROTECTION ASSOCIATION, http://www.horseprotection.it/dett_articolo.asp?id_a=379, *supra* Note 65.

[67] *See Pasture to Plate*, *supra* Note 48 ("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.").

[68] Patron Farms, LLC 7/9/12, Department of Health and Human Services Warning Letter CIN-12-302058-21 (attached here to as Exhibit 10) ("*Patron Farms Warning Letter*").

[69] 21 U.S.C. § 342(a)(4) ("A food shall be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. . . ."); 21 U.S.C. § 601(m)(4) ("Food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. . . ."); *Patron Farms Warning Letter*, Exh. 10. Given the typical purposes for which American horses are raised and the way they are treated, it is uncertain whether any American horses are raised under conditions in which medicated animals bearing potentially harmful drug residues are not likely to enter the food supply.

[70] *Patron Farms Warning Letter*, Exh. 10

government mandating an EU-like passport. The Canadian system certainly would not work, as that very system failed to identify the horse at issue as adulterated. The Ohio horse dealer admitted to simply signing the horse producer's name to the Equine Identification Document without inquiring into the medical status of the horse.[71] Notably, this farm is a regular seller of horses for slaughter, and was still engaging in this presumably routine practice. Given the frequency of this type of conduct, the primary function of the Canadian system seems to be to provide a false sense of comfort about the safety of meat from American horses.

Canada's certification system is especially inappropriate for American horses when, throughout their lives, virtually all American horses are administered banned and dangerous substances that render their flesh adulterated regardless of any residue showing. Given the difficulty of identifying individual horses and individual horse producers, it is difficult to view any certification that a particular horse's flesh is not adulterated as anything beyond a hope, a guess, or outright fraud.

**Horse Slaughter Is Not Needed to Reduce the Suffering of American Horses.**

Finally, the Petition falsely claims that horse slaughter is "much-needed" because of the presence of natural problems such as drought and fire. The lack of any logical connection between drought and fire, on the one hand, and excess horses, on the other, makes this claim frivolous. Obviously, the barbaric slaughter of horses to produce adulterated meat for foreign consumers is not a solution to drought and wild fires.

Wallis and her business partners may easily claim, without any possible supporting evidence, that slaughtering will prevent the potential for harm coming to the horses. But a prolonged and painful process ending with an inhumane death can not be seen as reducing suffering, any more than a slow torture-killing of a sick animal can be so characterized. If Wallis and her fellow profiteers are stopped, responsible horse rescue organizations exist who are willing to adopt horses from individuals unable to properly care for them. These programs are very active and ready to assist in the rescue of American horses going to slaughter. And if a horse is sick or injured, euthanization is another humane alternative. Slaughter is not a panacea, and it is not kind, as described above. As established when American slaughterhouses were still killing horses, the treatment the horses received stateside is equally as horrific as that currently going on north and south of the border.

[71] *Id.*

The decision to authorize horse slaughter should be made on the merits, not on the basis of misleading and dishonest assertions, and not to provide a disposal system for horses who Wallis claims are "unwanted," but whose numbers can be reduced and who can easily be integrated into life in America, if they are no longer sold for slaughter. Based on the lack of support for horse slaughter, the absence of American interest in horse meat, the expense of inspecting horses, the cruelty of horse slaughter, and the likelihood that meat from virtually all American horses is adulterated, we request that you deny any applications for horse slaughter inspections, and see the Wallis Petition for what it is—a profit-motivated piece of propaganda based not in fact, but in saying anything necessary (regardless of truth) in order to obtain business.

Very truly yours,

Bruce A. Wagman

BAW/mj
Attachments

SF\320363749.1

# EXHIBIT 1

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

# APPLICATION FOR FEDERAL INSPECTION
(Meat, Poultry, Egg Product, Catfish and Import Inspection)

**Instructions:** Submit this application to the District/Regional Office, Food Safety and Inspection Service, U.S. Department of Agriculture for import inspection requests. Complete all sections. If a section is not applicable, enter "N/A" or "None." If additional space is needed for any item, attach sheet and number the item.

## SECTION I. ESTABLISHMENT INFORMATION

1. Date of Application: April 25, 2012

2. Type of Application: ☑ New ☐ Change of Ownership ☐ Change of Location ☐ Application Extension

3. Type of Inspection Required *(Check box)*: ☑ Meat ☐ Poultry ☐ Egg Product ☐ Import

4. Form of Organization *(Check box)*: ☐ Individual ☐ Cooperative Association ☐ Partnership ☐ Corporation ☑ LLC

5. If Corporation, Name of State Where Incorporated: Limited Liability Company

6. Address of Corporate Headquarters: 100 N. Jefferson St. Mexico, Missouri 65265

7. Date Incorporated: April 3, 2012

8. Name of Applicant and Mailing Address *(Include zip code)*: Unified Equine, LLC 100 N. Jefferson St. Mexico, Missouri 65265

9. Federal Employer ID#: (b) (4)

10. Dun & Bradstreet #: None

11. Area Code and Telephone Number: 573-581-5280

12. Firm's Code (Import Only)

13. Actual Name of and Physical Address of Plant: American Beef Company 3400 Highway B P. O. Box 40 Rockville, Missouri 64780

14. Mailing Address If Different from Item 8 *(Include zip code)*

15. Area Code and Telephone Number: 660-200-2006

16. Attach Limits or Establishment Premises to be under Federal Inspection *(for egg plants attach blueprint)*: See Attached - 3400 Highway B, Rockville, Missouri 64780 - Exhibit A

17. Name and Establishment Number of other official establishments located in the same facility: None

18. Doing Business As: American Beef Company

19. *Month and Year when establishment will be ready to operate under inspection*: September 2012

20. *Comments*

## SECTION II. TYPE OF OPERATION

MEAT AND POULTRY INSPECTION ACTIVITIES *(Check all that apply.)*

21 A. Animals to be slaughtered when inspecting is inaugurated *(meat and poultry only)*

a. ☐ Beef ☐ Sheep ☐ Goats ☐ Swine ☑ Equine ☐ Chicken ☐ Turkeys ☐ Goose ☐ Ducks ☐ Guineas ☐ Squab ☐ Ratites

b. ☑ Raw - Ground *(Non-Intact Products)*

c. ☑ Raw - Not Ground (Intact Products)

d. ☐ Thermally Processed Commercially Sterile

e. ☐ Not Heat Treated - Shelf Stable

f. ☐ Heat Treated - Shelf Stable

g. ☐ Fully Cooked - Not Shelf Stable

h. ☐ Heat Treated but Not Fully Cooked - Not Shelf Stable

i. ☐ Product with Secondary Inhibitors - Not Shelf Stable

EGG PRODUCTS INSPECTION

21 B. Check the type of product intended for inspection at the establishment (Check all that apply)

a. ☐ Shell Egg Breaking

b. ☐ Thermally Processed *(Pasteurized heat treated)*

☐ Cans/Pails ☑ Flexible Pouches ☐ Jars ☑ Cartons ☑ Bag-n-Box ☑ Totes ☐ Tankers ☐ Other

c. ☐ Not Heat Treated - Unpasteurized egg product only

d. ☐ Heat Treated - Shelf Stable (Dried egg product, 50% Sugar Yolk)

e. ☐ Heat Treated But Not Fully Cooked - not shelf stable (liquid and frozen egg products)

IMPORT INSPECTION

21 C. Species (Check all that apply)

☐ Meat ☐ Poultry ☐ Egg Products ☐ Catfish

22. Check the type of product intended for inspection at the establishment *(Check all that apply)*

a. ☐ Raw - Non-Intact

☐ Ground ☐ Other Non-Intact

b. ☐ Raw - Intact

Carcasses: ☐ Beef ☐ Veal ☐ Veal Hide On ☐ Goats ☐ Pork ☐ Lamb

☐ Mutton ☐ Equine ☐ Poultry ☐ Ratites

Other: ☐ Cuts ☐ Boneless Manufacturing Meats ☐ Other Intact

c. ☐ Thermally Processed Commercially Sterile

☐ Cans ☐ Flexible Pouches ☐ Trays ☐ Jars

d. ☐ Not Heat Treated - Shelf Stable

e. ☐ Heat Treated - Shelf Stable

f. ☐ Fully Cooked - Not Shelf Stable

☐ Frozen from an APHIS restricted country (9CFR 94.4(b)) ☐ Frozen ☐ Perishable

g. ☐ Heat Treated But Not Fully Cooked - Not Shelf Stable

h. ☐ Product with Secondary Inhibitors - Not Shelf Stable

i. ☐ Shell Eggs/Egg Products

☐ Shell Eggs ☐ Liquid ☐ Frozen ☐ Dried

23. Mode of Transportation - Import Inspection Only *(Check all that apply)*

☐ Tankers ☐ Rail Cars ☐ Trucks ☐ Ocean Vessel ☐ Airline ☐ Other (*Specify*) _____

FSIS Form 5200-2 (2/14/2012) Page 3

| SECTION III | OWNERSHIP AND MANAGEMENT INFORMATION |
|---|---|

24. List all persons responsibly connected with the applicant. Include all owners, partners, officers, directors, holders or owners of 10 per centum or more of voting stock and employees in a managerial or executive capacity in the business. Notify the Division Director or Import Inspection Division Director of any changes in the listing given.

| Name and Title (Title - Indicate if partner or manager) | Present Home Address (Street and Number, City, State, Zip Code) | HOLDER OF 10% OR MORE VOTING STOCK (If Corp.) YES | NO |
|---|---|---|---|
| Dan K. Erdel, Manager | (b)(6) | ☐ | ☐ |
| Sue Wallis | (b)(6) | ☐ | ☐ |
| Susan Nelson | (b)(6) | ☐ | ☐ |
| | | ☐ | ☐ |
| | | ☐ | ☐ |
| | | ☐ | ☐ |

25. Enter the name of each person listed under Item 24 who has been convicted in any Federal or State court of any felony. Enter the name of each person listed under Item 24 who has been convicted in any Federal or State court of more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. Include the nature of the crime, the date of conviction and the court in which convicted. If none write "None."

None

26. List each conviction against the applicant (person, firm or corporation) in any Federal or State court of any felony, List each conviction against the applicant (person, firm or corporation) in any Federal or State court of more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. Include the nature of the crime, the date of conviction and the court in which convicted. If none write "None."

None

27. Sanitation Standard Operating Procedures have been developed for the establishment in accordance with §416.12 of the regulations. (Check one) ☑ YES ☐ NO Procedures being formulated

28. Applicant has been provided with a copy of this Privacy Act Notice. (Check one) ☑ YES ☐ NO

| 29. Typed Name of Person Signing Application | 30. Signature | 31. Title |
|---|---|---|
| Dan K. Erdel | Dan K. Erdel | Manager |

TO BE COMPLETED BY USDA, FSIS

32. Is this establishment presently under state inspection? (OFO only) ☐ YES ☐ NO

33. Is this establishment to be under Talmadge-Aiken Act? (OFO only) ☐ YES ☐ NO

| 34. Official Inspection Number Reserved | 35. Signature of DM or IID Director | 36. Date |
|---|---|---|
| 00637 E | | |

100 N Jefferson St.
Mexico, MO 65265
573-581-5280
573-581-1353 (fax)

BRETT, ERDEL, OWINGS & TANZEY P.C.

106 N. Sturgeon Street
Montgomery City, MO 63361
573-564-3713
573-564-6158 (fax)

# Fax

**To:** Dr. Gilmore **From:** Kathryn

**Fax:** 785-841-5623 **Pages:** 6

**Phone:** **Date:** 4/25/12

**Re:** Unified Equine, LLC **cc:**

☐ Urgent ☐ For Review ☐ Please Comment ☐ Please Reply ☐ Please Recycle

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL Kathryn AS SOON AS POSSIBLE AT (573) 581-5280.

**EXHIBIT A**

The following described real estate located in Bates County, Missouri:

**All of the North 830.9 feet of that part of the Southeast Quarter of the Southeast quarter of Section 11, lying East of the Missouri Kansas and Texas Railroad right-of-way, except a strip off the East side thereof, heretofore conveyed to the State of Missouri for highway purposes, all in Township 38, of Range 29, Bates County, Missouri. Subject to easements and road rights-of-way as the same may now exist. Subject to easements, restrictions and reservations now of record.**

**Together with all easements for ingress/egress, water, gas, electric, sewer, and telephone or other utilities now serving the premises.**

Together with all buildings and improvements on the real estate and all of the Seller's right, title and interest in and to all adjacent lands, rights, roads, alleys, ways, waters, privileges and easements and appurtenances thereunto belonging or in anywise appertaining.

LAW OFFICES
**BRETT, ERDEL, OWINGS & TANZEY, P.C.**
A MISSOURI PROFESSIONAL CORPORATION

BRADFORD A. BRETT
DAN K. ERDEL
RANDAL J. OWINGS
CARLA WOOD TANZEY
JASON E. NEWTON

100 NORTH JEFFERSON
MEXICO, MISSOURI 65265-2725
TELEPHONE 573-581-5280
FAX 573-581-1353

106 NORTH STURGEON
MONTGOMERY CITY, MISSOURI 63361
TELEPHONE 573-564-3713
FAX 573-564-6158

April 25, 2012

Dr. Keith Gilmore, District Manager
United States Department of Agriculture
FAX: 785-841-5623

RE: Application for Federal Inspection – Unified Equine, LLC

Dear Dr. Gilmore:

As we discussed on the telephone, please find enclosed an Application for Federal Inspection, Form 5200-2, related to the Rockville processing plant in Rockville, Missouri. I am sure Darrell Cruea will be in touch with you to make final decisions on the date and time of the inspection. Thank you for your courtesy in this matter.

Sincerely yours,

**BRETT, ERDEL, OWINGS & TANZEY, P.C.**

BY: _____

**DAN K. ERDEL**

DKE:jlb

Enclosure

# EXHIBIT 2

Collection of this information is voluntary. It is needed before Federal inspection of meat and poultry is granted. It is used by FSIS to determine whether the applicant should be issued a grant of inspection. (9 CFR 304.1 and 9 CFR 381.16) FORM APPROVED OMB 0583-0082

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

# APPLICATION FOR FEDERAL MEAT, POULTRY, OR IMPORT INSPECTION

**INSTRUCTIONS:**
Submit this application to the District Manager, Food Safety and Inspection Service, U.S. Department of Agriculture for applicable inspection requests. Complete all sections. If a section is not applicable enter "N/A" or "None." If additional space is needed for any item, attach sheet and number the item.

## SECTION I *(to be completed for Import or Domestic Inspection Activities)*

1. DATE OF APPLICATION: 12-13-2011

2. TYPE OF APPLICATION: ☐ NEW ☐ CHANGE OF OWNER ☐ CHANGE OF LOCATION ☒ OTHER (Specify) Species Addition

3. TYPE OF INSPECTION REQUIRED: ☒ MEAT ☐ IMPORT ☒ POULTRY

4. EXEMPTED ACTIVITIES (specify): Custom Slaughter and processing | Retail

5. FORM OF ORGANIZATION: ☐ INDIVIDUAL ☐ COOPERATIVE ASSOCIATION ☐ PARTNERSHIP ☐ CORPORATION ☒ OTHER (specify) Limited Liability Co.

6. IF CORPORATION; NAME OF STATE WHERE INCORPORATED: New Mexico

7. DATE INCORPORATED (Month and Year): MAY 2010

8. NAME OF APPLICANT (Company Name) AND MAILING ADDRESS (Include Zip Code):
Valley Meat Co. LLC
3845 Cedarvale Rd.
Roswell, NM 88203

FEDERAL EMPLOYER IDENTIFICATION NO. (As assigned by Internal Revenue Service): (b) (6)

9. AREA CODE TELEPHONE NUMBER: (b) (6)

10a. LOCATION OF PLANT AND MAILING ADDRESS IF DIFFERENT FROM ITEM 8 (Include Zip Code): N/A

11. AREA CODE TELEPHONE NUMBER

10b. ATTACH A DESCRIPTION OF THE LIMITS OF THE ESTABLISHMENT PREMISES THAT IS REQUESTED TO BE UNDER FEDERAL INSPECTION (e.g., Diagram, written narrative, or schematic)

12. NAME AND ESTABLISHMENT NUMBER OF OTHER ESTABLISHMENTS LOCATED IN THE SAME FACILITY: N/A

13. OTHER NAMES (If any) UNDER WHICH BUSINESS WILL BE CONDUCTED

| 14. DAYS PER YEAR PLANT WILL OPERATE | | 15. HOURS PER WEEK PLANT WILL OPERATE | | 16. HOURS PER DAY PLANT WILL OPERATE | | 17. MONTH AND YEAR WHEN PLANT WILL BE READY TO OPERATE UNDER INSPECTION PROGRAM | |
|---|---|---|---|---|---|---|---|
| EXEMPT | NON-EXEMPT | EXEMPT | NON-EXEMPT | EXEMPT | NON-EXEMPT | EXEMPT | NON-EXEMPT |
| 260 | 260 | 10 | 40 | 2 | 8 | — | OPEN NOW |

## SECTION II *(to be completed for Domestic Inspection Activities)*

**SLAUGHTER**

18. ANIMALS TO BE SLAUGHTERED WHEN INSPECTION IS INAUGURATED

SLAUGHTER ONLY: ☒ CATTLE ☒ CALVES ☒ SHEEP ☒ GOATS ☒ SWINE ☒ EQUINES ☐ YOUNG CHICKENS ☐ MATURE CHICKENS ☐ TURKEYS ☐ GEESE ☐ DUCKS ☐ GUINEAS

19. FRESH MEAT OR READY-TO-COOK POULTRY TO BE DISPOSED OF IN COMMERCE 1/

COMMERCE ONLY: ☒ BEEF ☒ VEAL ☒ LAMB OR MUTTON ☒ GOAT MEAT ☒ PORK ☒ EQUINE MEAT ☐ YOUNG CHICKENS ☐ MATURE CHICKENS ☐ TURKEYS ☐ GOOSE ☐ DUCK ☐ GUINEA

**PROCESSING**

20. PREPARED OR PROCESSED WHEN INSPECTION IS INAUGURATED

TYPE OF PRODUCT: ☐ MEAT ☐ POULTRY ☒ BOTH

a. ☒ BREAKING/CUTTING (carcasses, primal cuts, whole poultry, poultry parts etc.)
b. ☒ BONING (manual boning meat/poultry)
c. ☐ MECHANICAL DEBONING (mechanical deboning meat/poultry)
d. ☒ FABRICATING (roast, steaks, chops, ground beef, hamburger etc.)
e. ☐ CURING (pork cuts, beef cuts, turkey, ham etc.)
f. ☐ FORMULATING (fresh/cured sausages, loaves, poultry rolls, patties mix etc.)
g. ☐ COOKING/SMOKING (pork cuts, beef cuts, sausage, loaves etc.)
h. ☐ CANNING (Shelf stable, perishable, cans, pouches, glass)
i. ☐ DRYING (pork cuts, beef cuts, sausage, dehydrated products)
j. ☐ CONVENIENCE ITEMS (entrees, dinners, pies, pizzas etc.)
k. ☐ SLICING (bacon, luncheon meats sausage etc.)
l. ☐ FATS/OILS (lard, tallow, shortening, margarine etc.)
m. ☐ OTHER (specify)

FSIS FORM 6200-2 (REVERSE)

## SECTION III *(to be completed for Import Inspection Activities)*

21. IMPORT INSPECTION ACTIVITIES

a. CARCASSES
- ☐ BEEF
- ☐ VEAL
- ☐ SWINE
- ☐ SHEEP
- ☐ GOATS
- ☐ EQUINE
- ☐ VENISON
- ☐ OTHER *(describe)*

b. FRESH
- ☐ CUTS
- ☐ BONELESS MFG MEAT

c. FROZEN MFG. MEATS
- ☐ CUTS
- ☐ BONELESS MFG MEAT

d. COOKED BEEF
- ☐ RESTRICTED
- ☐ UNRESTRICTED

e. CONTAINERS
- ☐ PERISHABLE
- ☐ SHELF STABLE

f. PROCESSED PRODUCTS
- ☐ FRESH/FROZEN
- ☐ HEATED
- ☐ DRIED/SEMI-DRIED

g. POULTRY (Whole Carcass)
- ☐ RAW
- ☐ COOKED

h. POULTRY (Parts)
- ☐ RAW
- ☐ COOKED
- ☐ OTHER POULTRY *(describe)*

## SECTION IV *(to be completed for Import and Domestic Inspection Activities)*

22. List all persons responsibly connected with the applicant. Include all owners, partners, officers, directors, holders or owners of 10 per centum or more of voting stock, and employees in a managerial or executive capacity in the business. Notify the District Manager of any changes in the listing given.

| NAME / TITLE *(indicate if partner, manager)* | SOCIAL SECURITY NO. | DATE OF BIRTH | PLACE OF BIRTH *(City and State)* | PRESENT HOME ADDRESS *(Street and Number, City, State, Zip Code)* | HOLDER OF 10% OR MORE VOTING STOCK *(If Corp)* YES (X) | NO (X) |
|---|---|---|---|---|---|---|
| Ricardo DeLos Santos Member | (b) (6) | (b) (6) | | (b) (6) | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

23. Enter the name of each person listed under item 22 who has been convicted in any Federal or State court of any felony. Enter the name of each person listed under item 22 who has been convicted in any Federal or State court of more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. Include the nature of the crime, the date of conviction and the court in which convicted. If none write "None."

NONE

24. List each conviction against the applicant *(person, firm or corporation)* in any Federal or State court of any felony. List each conviction against the applicant *(person, firm or corporation)* in any Federal or State court of more than one violation of any law, other than a felony, based upon the acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food or upon fraud in connection with transactions in food. Include the nature of the crime, the date of conviction and the court in which convicted. If none write "None."

NONE

25. *SANITATION STANDARD OPERATING PROCEDURES HAVE BEEN DEVELOPED FOR THE ESTABLISHMENT IN ACCORDANCE WITH §416.12 OF THE REGULATIONS. (Check)* ☒ YES ☐ NO

26. *APPLICANT HAS BEEN PROVIDED WITH A COPY OF THE PRIVACY ACT NOTICE (Check)* ☒ YES ☐ NO

**AGREEMENT AND CERTIFICATION:** If inspection is granted under the application, I *(we)* expressly agree to conform strictly to the Federal Meat Inspection Act *(21 U.S.C. 601 et seq.)*, the Regulations Governing the Meat Inspection of the United States Department of Agriculture *(9 CFR Part 301 et seq.)*, or the Poultry Products Inspection Act *(21 U.S.C. 451 et seq.)*, and the Poultry Products Inspection Regulations *(9 CFR 381 et seq.)*, or both *I CERTIFY that all statements made herein are true to the best of my knowledge and belief.*
**WARNING:** Persons willfully making false, fictitious, or fraudulent statements or entries are subject to $10,000 fine or imprisoned not more than five years or both as prescribed by Title 18 U.S. Code 1001.

This is an Equal Opportunity Program. If you believe you have been discriminated against because of race, color, religion, sex, national origin, age or handicap, write immediately to the Secretary of Agriculture or the Administrator, FSIS, Washington, D.C. 20250.

| 27. TYPED NAME OF PERSON SIGNING APPLICATION | SIGNATURE AND TITLE OF OWNER, PARTNER, OR AUTHORIZED OFFICER MAKING THIS APPLICATION | |
|---|---|---|
| Ricardo DeLos Santos | 28. SIGNATURE | 29. TITLE: Member |
| 30. OFFICIAL NUMBER ASSIGNED/RESERVED: EST 7299 P. 7299 E 371 | | 31. IS THIS PLANT PRESENTLY UNDER STATE INSPECTION *(Completed by District Office)* ☐ YES ☐ NO |

**TO BE COMPLETED BY USDA**

| 32. DATE RECEIVED | 33. DATE REVIEWED | 34. THIS PLANT TO BE UNDER TALMADGE-AIKEN ACT ☐ YES ☐ NO |
|---|---|---|

35. SIGNATURE OF DISTRICT MANAGER | 36. DATE

# EXHIBIT 3

NEW MEXICO
ENVIRONMENT DEPARTMENT

*Environmental Protection Division*
*Solid Waste Bureau*

SUSANA MARTINEZ
Governor
JOHN A. SANCHEZ
Lieutenant Governor

1190 St. Francis Drive, Room S2050
P.O. Box 5469
Santa Fe, New Mexico 87502-5469
Telephone (505) 827-0197
Fax (505) 827-2902
www.nmenv.state.nm.us

DAVE MARTIN
Secretary
BUTCH TONGATE
Deputy Secretary

**Certified Mail – Return Receipt Requested No. 7011 3500 0000 0328 3210**

August 2, 2012

Ricardo De Los Santos, Agent
Valley Meat Company, LLC
3845 Cedarvale Road
Roswell, New Mexico 88203

Dear Mr. De Los Santos:

Please find the enclosed Administrative Compliance Order ("Order"), No. SWB 12-16 (CO), issued to Valley Meat Company, LLC by the Secretary of the New Mexico Environment Department ("NMED") through his designee, Mary E. Rose, Acting Director, Environmental Protection Division. The Order alleges violations of the Solid Waste Act, NMSA 1978, §§ 74-9-1 to 74-9-42, and the New Mexico Solid Waste Rules, 20.9.2 – 20.9.10 NMAC, for the failure to register a composting facility and for failing to dispose of several thousand cubic yards of previously-composted material disposed upon the ground at Valley Meat Company's Roswell, New Mexico business location. The Order compels compliance and assesses a civil penalty of $86,400.00.

The Order imposes certain requirements upon Valley Meat Company, LLC concerning its answer and defenses, and provides certain rights, including the right to a public hearing. These requirements and rights are stated within the Order. If you have any questions, or if you wish to schedule a pre-hearing settlement conference, please call me at (505) 827-2924.

Sincerely,

George W. Akeley Jr. (Chuck)
Manager, Enforcement Section

Enclosure – Administrative Compliance Order No. SWB 12-16 (CO)

STATE OF NEW MEXICO
ENVIRONMENT DEPARTMENT

| | | |
|---|---|---|
| **NEW MEXICO ENVIRONMENT DEPARTMENT,** | ) | |
| **Complainant,** | ) | **No. SWB 12-16 (CO)** |
| **v.** | ) | |
| **VALLEY MEAT COMPANY, LLC,** | ) | |
| **Respondent.** | ) | |

## ADMINISTRATIVE ORDER REQUIRING COMPLIANCE AND ASSESSING A CIVIL PENALTY

Pursuant to the New Mexico Solid Waste Act ("SWA"), NMSA 1978, §§ 74-9-1 to 74-9-42, the Secretary of the New Mexico Environment Department ("NMED"), acting through his designee, the Director of the Environmental Protection Division, issues this Administrative Compliance Order ("Order") to Valley Meat Company, LLC ("Respondent"), to assess a civil penalty for violations of the SWA and the New Mexico Solid Waste Rules ("SWR"), 20.9.2 – 20.9.10 NMAC, and to compel compliance with the SWA and the SWR.

## FINDINGS OF FACT

1. Complainant is an agency of the executive branch of New Mexico state government and is charged with the administration and enforcement of the SWA and the SWR.

2. Respondent is a for-profit New Mexico corporation with its principal address at 3845 Cedarvale Road, Roswell, New Mexico 88203-9020. Respondent owns and operates a livestock slaughter and processing business ("facility") and is engaged in composting the resulting offal, a special waste as defined by the SWA and SWR. Respondent's organizer and registered agent is Ricardo De Los Santos.

3. Respondent is a "person," as defined in the SWA, NMSA 1978, § 74-9-3.I, and 20.9.2.7.P(2) NMAC.

4. Respondent's slaughterhouse, processing and composting operations are located at 3845 Cedarvale Road, Roswell, New Mexico.

5. Pursuant to 20.9.2.7.C(12) NMAC, "compost" means "organic material that has undergone a controlled process of biological decomposition and pathogen reduction, and has been stabilized to a degree that the final product is potentially beneficial to plant growth and can be used as a soil amendment, growing medium amendment or other similar uses."

6. Pursuant to 20.9.2.7.C(13) NMAC, "composting" means "the process by which biological decomposition of organic material is carried out under controlled conditions. The process stabilizes the organic fraction into a material which can be easily and safely stored, handled and used in an environmentally acceptable manner."

7. Pursuant to 20.9.2.7.C(14) NMAC, "composting facility" means "a facility, other than a transformation facility, that is capable of providing biological stabilization of organic material."

8. Pursuant to 20.9.2.7.S(13) NMAC, "special waste" means "solid waste that has unique handling, transportation, or disposal requirements to assure protection of the environment and the public health, welfare and safety," and includes packing house and killing plant offal.

9. Pursuant to 20.9.2.10.A(1) NMAC, no person shall "store, process, or dispose of solid waste except by means approved by the secretary and in accordance with [Environmental Improvement Board] regulations...".

10. Pursuant to 20.9.2.10.A(3) NMAC, no person shall "dispose of any solid waste in a place other than a solid waste facility that meets the requirements of [the SWR]...".

11. Pursuant to 20.9.3.27.A(2) NMAC, the owner or operator of a composting facility that accepts only source separated compostable materials shall file an application for a registration with the NMED at least 30 days prior to any operations and every five years thereafter.

12. Pursuant to 20.9.3.27.A NMAC, "[f]acilities covered by this section [20.9.3.27 NMAC] that do not timely file a complete application for registration are hereby deemed unpermitted solid waste facilities, and the owner or operator may be subject to penalties, permit requirements and nuisance abatement orders."

13. Respondent's facility is a composting facility as defined by the SWR.

14. On April 7, 2010, the NMED telephonically informed Respondent of the requirement to register its composting operation and the requirement to send a company representative for training to become a certified compost facility operator. On the same day, a subsequent electronic mail was sent to Respondent providing internet links to the webpage of the Solid Waste Bureau of the NMED ("SWB") explaining the requirements of the SWR and links to the Composting Facility Registration Form.

*May 13, 2010 Inspection*

15. On May 13, 2010, a NMED enforcement officer, accompanied by the Chief of the NMED's Solid Waste Bureau ("SWB"), inspected Respondent's facility to determine compliance with the SWR.

16. During the May 13, 2010 inspection, the NMED enforcement officer observed and recorded, or otherwise verified that Respondent:

A. Failed to register its composting operation, as a Composting Facility Registration Form had not been provided to the NMED. A copy of the necessary registration form was left with Respondent during the inspection. Respondent agreed to submit the registration form to the NMED's SWB within two weeks of the inspection;

B. Failed to properly dispose of solid waste, specifically thousands of cubic yards of aged, previously-composted and stockpiled material consisting of bones, hides, and heads mixed with manure, located along the southeast corner of the property. Additionally, the inspection documented an active offal composting operation at a covered, canopy area located adjacent to the old stockpiled material; and

C. Failed to properly compost offal, as evidenced by protruding and/or uncovered animal parts (offal) and entire carcasses in the active composting piles located at the covered, canopy storage area.

*December 10, 2010 Inspection*

17. On December 10, 2010, a NMED enforcement officer performed a follow up inspection of Respondent's facility to determine compliance with the SWR.

18. During the December 10, 2010 inspection, the NMED enforcement officer observed and recorded, or otherwise verified that Respondent:

A. Failed to register a composting facility, as Respondent failed to submit a registration form, as agreed to by Respondent during the telephonic discussion of April 7, 2010 and during the NMED SWB's May 13, 2010 inspection; and

B. Failed to properly dispose of solid waste – specifically, the previously composted and stockpiled material, as Respondent had not removed any of this material for proper disposal, as discussed during the NMED SWB's May 13, 2010 inspection.

19. On January 4, 2011, the NMED's SWB issued a Notice of Violation ("NOV") to Respondent, documenting Respondent's failure to register a composing facility, the improper composting of a special waste (offal), and the failure to properly dispose of solid waste (previously composted material). The NOV requested voluntary compliance and a response to the NMED, in writing, within ten (10) days of receipt. The response was to include submission of a completed Composting Facility Registration Form and a written abatement plan for the removal and proper disposal of the previously composted material.

20. On January 7, 2011, the NMED's SWB received Respondent's Composting Facility Registration Form.

21. On January 14, 2011, Respondent replied to the NOV, in part, stating that a Composting Facility Registration Form had been submitted and that the improper composting of special waste (offal) had been corrected. Regarding the previously composted material,

Respondent asserted that it would begin processing the material to remove large items of bone and seek a landfill to which the material could be sent for disposal.

*April 18, 2012 Inspection*

22. On April 18, 2012, a NMED enforcement officer performed a follow up inspection of Respondent's facility to determine compliance with the SWR.

23. During the April 18, 2012 inspection, the NMED enforcement officer observed and recorded, or otherwise verified that Respondent:

A. Failed to register a composting facility, as Respondent's offal composting operations were continuing, and the Compost Facility Registration Form received by the SWB on January 7, 2011 had not been approved and a Certificate of Registration had not been issued; and

B. Failed to properly dispose of solid waste – specifically the previously composted and stockpiled material, as Respondent had not removed any of this material for disposal, as required in the NMED SWB's January 4, 2011 NOV. The NMED enforcement officer provided Respondent with a copy of a letter dated January 31, 2012, in which the operator of the Roswell Municipal Landfill agreed to accept Respondent's previously composted and stockpiled material for disposal. The NMED enforcement officer advised Respondent that this waste needed to be disposed within 30 days.

*April 26, 2012 Inspection*

24. On April 26, 2012, a NMED enforcement officer conducted a follow-up inspection of Respondent's facility to determine compliance with the SWR.

25. During the April 26, 2012 inspection, the NMED enforcement officer observed and recorded, or otherwise verified that Respondent:

A. Failed to register a composting facility, as Respondent's offal composting operations were continuing, and the Compost Facility Registration Form received by the SWB on January 7, 2011 had not been approved and a Certificate of Registration had not been issued; and

B. Failed to properly dispose of solid waste – specifically the previously composted and stockpiled material, as Respondent had not removed any of this material for disposal, as discussed during the NMED SWB's inspection of April 18, 2012.

26. On April 28, 2012, Respondent began transportation and disposal of the first truckloads of the previously composted and stockpiled material at the Roswell Municipal Landfill. Landfill records available to the NMED indicate that five loads were transported to the landfill on that day, totaling 95.69 tons of waste. Additional loads were transported to the landfill on April 30, 2012 and May 12, 15, 17, 18, 24-26 and 30, 2012. However, upon information and belief, as of the issuance date of this Order, approximately 50% of the previously composted and stockpiled material remains at Respondent's facility and transportation of additional loads of the waste to the landfill have ceased.

27. On June 7, 2012, the NMED denied Respondent's composting facility registration application. Denial of the application was based on insufficient responses to the NMED's requests for additional information relating to Respondent's operations plan, the failure to complete the registration in a timely manner, and Respondent's lack of a consistent effort to assure timely removal of the stockpiles and to find alternatives for disposal of the offal waste generated from the slaughterhouse operation.

## CONCLUSIONS OF LAW

28. Paragraphs one (1) through 27 are incorporated herein by reference.

Violation No. 1

Failure to Register a Composting Facility

29. In violation of the SWR, 20.9.3.27.A(2) NMAC, Respondent failed to register its offal composting operation, one instance of violation, occurring on or before October 11, 2010 to on or after December 9, 2010 (a period of 60 days).

Violation No. 2

Failure to Properly Dispose of Solid Waste

30. In violation of the SWA, NMSA 1978, § 74-9-31.A(1)(a), and the SWR, 20.9.2.10.A(1) and (3) NMAC, Respondent failed to properly dispose of several thousand cubic yards of solid waste comprised of previously-composted and stockpiled material that was abandoned upon the ground at Respondent's business property, one instance of violation, occurring on or before February 18, 2012 to on or after April 17, 2012 (a period of 60 days).

## CIVIL PENALTY

31. Section 74-9-36.B of the SWA authorizes the assessment of civil penalties of up to Five Thousand Dollars ($5,000) per day for each violation of the SWA or the SWR. The NMED hereby assesses a civil penalty of Eighty-Six Thousand and Four Hundred Dollars ($86,400) for Respondent's two (2) violations. The penalty is calculated based on the factors set forth in the NMED's Solid Waste Civil Penalty Assessment Policy and upon such other factors as justice may require. The individual penalty for each violation is:

| Violation | | Amount |
|---|---|---|
| No. 1 | Failure to Register a Composting Facility | $48,000 |
| No. 2 | Failure to Properly Dispose of Solid Waste | $38,400 |

32. Payment shall be made by certified or cashier's check payable to the State of New Mexico and mailed or hand delivered to George W. Akeley Jr. (Chuck), Manager, Enforcement Section, Solid Waste Bureau, NMED, Harold Runnels Building, Room S-2062, 1190 St. Francis Drive, P.O. Box 5469, Santa Fe, New Mexico 87502-5469.

## SCHEDULE OF COMPLIANCE

33. Based on the foregoing findings and conclusions, and pursuant to the SWA, NMSA 1978, § 74-9-36.A(1), Respondent is hereby ordered to comply with the following schedule of compliance:

A. Upon Receipt of this Order, Respondent shall cease offal composting operations;

B. No later than fifteen (15) days after the receipt of this Order, Respondent shall contact the NMED to discuss the requirements of this Order;

C. Within thirty (30) days of receipt of this Order, Respondent shall submit to the NMED an abatement plan addressing cleanup and removal of the remaining previously composted and stockpiled material, and the proposed disposition for any on-site offal that is being stored or actively composted at the Facility at the time this Order was issued; and

D. Within forty-five (45) days of receipt of this Order, Respondent shall pay the penalty.

**NOTICE**

34. For failure to take corrective action and timely comply with the foregoing requirements of this Order, the Secretary of the NMED, pursuant to the SWA, NMSA 1978, § 74-9-36.C, may seek to assess additional civil penalties of not more than Ten Thousand Dollars ($10,000) for each day of non-compliance with the Order.

**NOTICE OF OPPORTUNITY TO ANSWER AND REQUEST A HEARING**

35. Under the SWA, § 74-9-36.G, this Order shall become final unless, no later than thirty (30) days after the Order is served, Respondent submits a written request to the Secretary for a public hearing to: Sally Worthington, Hearing Clerk, Office of the Secretary, NMED, Harold Runnels Building, Room N-2150, 1190 St. Francis Drive, P.O. Box 5469, Santa Fe, New Mexico 87502-5469. A copy of this Order must be attached to the Request for Hearing.

36. Pursuant to 20.1.5.200.A(2) NMAC governing the NMED's Adjudicatory Procedures, Respondent's Request for Hearing shall include an Answer.

37. Pursuant to 20.1.5.200.A(2)(a) NMAC, Respondent's Answer shall clearly and directly admit, deny or explain each of the factual allegations contained in the Order with regard to which Respondent has any knowledge. Where Respondent has no knowledge of a particular factual allegation, Respondent should so state, and Respondent may deny the allegation on that basis. Any allegation of the Order not specifically denied shall be deemed admitted.

38. Pursuant to 20.1.5.200.A(2)(b) NMAC, Respondent's Answer shall also include any affirmative defenses upon which Respondent intends to rely. Any affirmative defenses not asserted in the Answer and Request for Hearing, except a defense asserting lack of subject matter jurisdiction, shall be deemed waived.

39. Pursuant to 20.1.5.200.A(2)(c) NMAC, the Answer shall be signed under oath or affirmation that the information contained therein is to the best of the signer's knowledge true and correct.

40. The public hearing shall be governed by the NMED's Adjudicatory Procedures, 20.1.5 NMAC.

**FINALITY OF ORDER**

41. This Order shall become final unless Respondent files a Request for Hearing and Answer within thirty (30) days after receipt of this Order. Unless a hearing is requested and an Answer filed in writing, the penalty proposed in this Order shall become due and payable as set forth in the Schedule of Compliance.

**SETTLEMENT CONFERENCE**

42. Whether or not Respondent submits a Request for Hearing and files an Answer, Respondent may confer with the NMED concerning settlement. The NMED encourages settlement consistent with the provisions and objectives of the SWA and the SWR. Settlement discussions do not extend the thirty (30) day deadline for filing an Answer and Request for Hearing, or alter the deadlines for this Order. Settlement discussions may be pursued as an alternative to and simultaneously with the hearing proceedings. Respondent may appear at the settlement conference *pro se* (without legal counsel) or may be represented by legal counsel.

43. Any settlement reached by the parties must be consistent with the SWA and the SWR. Any settlement must be approved by the Secretary of the NMED and shall be a Stipulated Final Order signed by the parties. The Stipulated Final Order must contain all of the requirements of 20.1.5.600 NMAC.

44. To explore the possibility of settlement in this matter, you may contact R. Cook Flynn, General Counsel, Office of General Counsel, New Mexico Environment Department, P.O. Box 5469, Santa Fe, New Mexico 87502-5469, (505) 827-2855.

45. Compliance with the requirements of this Order does not relieve Respondent of the obligation to comply with all other applicable laws and regulations.

## TERMINATION

46. This Order shall terminate when Respondent certifies that all the requirements of this Order have been met, and the NMED has approved such certification, or when the Secretary approves a Stipulated Final Order.

Butch Tongate
for Mary E. Rose, Director (Acting)
Environmental Protection Division
New Mexico Environment Department

8/2/12
Date

## CERTIFICATE OF SERVICE

I hereby certify that the foregoing Administrative Compliance Order was mailed via certified mail, return receipt requested, No. 7011 3500 0000 0328 3210, postage prepaid on this 2nd day of August, 2012, to the following person:

Ricardo De Los Santos, Agent
Valley Meat Company, LLC
3845 Cedarvale Road
Roswell, New Mexico 88203

Sara L. Martinez

Sara Martinez, Administrative Secretary
Solid Waste Bureau

# EXHIBIT 4

## DECLARATION OF PEGGY W. LARSON, DVM, MS, JD

I, Peggy W. Larson, declare as follows:

1. I am a doctor of veterinary medicine, currently practicing in Vermont. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. As described in the attached Curriculum Vitae, I am a licensed large animal veterinarian and have been practicing veterinary medicine for over 45 years. I received a Doctorate of Veterinary Medicine from the University of Ohio in 1965, a Masters of Science in comparative pathology from the University of California at Davis in 1968, and a Juris Doctorate from Vermont Law School in 1988.

3. From 1968 to 1978, I was a practicing large animal veterinarian in North Dakota, focusing on food animal and equine medicine and surgery. I performed diagnosis, treatment, and surgery, and frequently assessed, observed, and treated horses in my professional capacity.

4. I served as a Veterinary Medical Officer for the United States Department of Agriculture (USDA) from 1979 to 1985. In this capacity, I managed federal livestock disease control programs in Vermont, performed animal welfare inspections at circuses and research facilities, and issued federal health certificates on export animals.

5. In 1984, I was appointed by the Governor of Vermont to the position of Vermont State Veterinarian and Acting Chief of Livestock and Meat Inspection. In this position, I managed ongoing livestock and meat inspections programs and rewrote Vermont's meat and poultry inspection regulations. For approximately four months, I inspected all of Vermont's slaughter facilities until a permanent veterinary meat inspector was hired.

6. As a veterinarian and a former USDA employee, I am familiar with the variety of drugs, substances and treatments given to American horses. I also have personal

knowledge regarding the issues surrounding the slaughtering of horses for human consumption, including the sources from which horses for human consumption originate, and horse slaughter welfare issues in general. As a large animal veterinarian, I have observed horses first hand in small and large communities throughout the country.

7. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue. Based on my experience and knowledge of the industry, I am informed and believe that many of the drugs, substances and treatments listed on Exhibit 1 are commonly used on American horses in the companion, competitive and sport areas. Many of those drugs are prohibited for use in horses intended for human consumption, and others have never been tested on humans to determine the effect of ingestion, or the degree to which any residue of these drugs, treatments and substances remains in horses who have been exposed to them.

8. Based on longstanding medical and scientific principles, it is impossible to declare horse meat safe for human consumption when the horses who are slaughtered for that meat have been exposed to an unidentified (and unidentifiable) number of drugs, treatments and substances, in unknown (and unknowable) quantities, at various times during their life.

9. In order for horse meat to be safe for human consumption, each of these drugs will have to be identified and the following will have to be determined: the length of time the drug is present in the horse after the last administration of the drug, what drug residuals remain after a specified waiting period, how much residue is allowable in the meat, and the toxic effects of the drug in humans, including humans who may have special sensitivities or medical conditions that may make them more susceptible to these drugs.

10. In order for horse meat to be safe for human consumption, a testing method will have to be developed to identify and quantify each of the drugs, treatments and

substances commonly used on American horses. Until these criteria are met, horse meat has to be deemed unsafe for human consumption.

11. Based on the foregoing and my training and experience, it is my professional opinion that American horses who are sent to slaughter for human consumption have potentially been treated with a variety of drugs, treatments and substances that potentially renders their flesh dangerous to people who eat horse meat and makes the horses' meat unsafe for human consumption.

12. Horses bound for slaughter are frequently shipped for long distances, and sometimes in a manner that fails to accommodate their unique temperaments and physical requirements. 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). Transported horses are often not given food and water every 28 hours, despite the federal law. T.H. Friend, *A Review of Recent Research on the Transportation of Horses*, 79 J. ANIMAL SCI. E32 (2001) ("Continuous transport of slaughter horses for 30 hours is common, and some trips last 36 hours or longer.").

13. Because of the methods of transport, horses often suffer a variety of injuries and illnesses during transport. *See, e.g.*, K.A. Houpt & S. Lieb, *Horse Handling and Transport*, LIVESTOCK HANDLING AND TRANSPORT (2000) (describing "moderately severe back injuries" in transported horses); G. Giovangnoli, M. Trabalza Marinucci, A. Bolla & A. Borghese, *Transport Stress in Horses: An Electromyographic Study on Balance Preservation*, 73 LIVESTOCK PRODUCTION SCIENCE 247 (2002). The lack of proper food and water in already weakened animals can lead to further injuries, illness and death during extended transport.

14. Consequently, many horses may arrive at the slaughterhouse too sick or injured to stand up and walk. If they are ill, the microorganisms and other infecting agents would taint their meat and render it unsafe for human consumption.

15. The horses that survive transport are put into holding pens at the slaughter plant. These pens often lack shelter and expose the horses to extreme temperatures, rain and snow. This further increases the chances of disease and infection, and the possibility that the horses' meat will have dangerous microorganisms or other problems that could make their flesh dangerous if it was turned into meat.

16. As summarized in one study, "slaughter 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." Gary D. Anderson & Don R. Lee, *Salmonella in Horses: A Source of Contamination of Horsemeat in a Packing Plant Under Federal Inspection*, 31 APPLIED AND ENVIRONMENTAL MICROBIOLOGY 661 (1975). This type of situation creates great potential for the growth of bacteria that can lead to severe health problems in humans who eat the meat of these horses.

17. During my tenure as a meat inspector in Vermont, I inspected slaughter animals, mostly dairy cattle. I became quite familiar with the behavior of these animals as they proceeded through the slaughter process. Even tame dairy cattle can become quite agitated in a slaughter plant. These animals are away from familiar surroundings, often for the first time in their lives, and they are often forced to move with an electric prod and they react accordingly.

18. Horses are more easily frightened than cattle. Horses can become particularly frightened, because they are historically prey animals. Consequently, based on my experience with large domestic animals, I believe that horses are uniquely unsuited to processing at a slaughter plant. It is very difficult to secure a horse's head which diminishes the effectiveness of the captive bolt. Sometimes horses have to be hit several times with the captive bolt, causing tremendous suffering before they are effectively rendered unconscious. Subsequently, it is highly probable that some horses may not be rendered unconscious when hung and bled.

Horses are also more likely to injure themselves trying to escape the runway in the slaughter plant.

19. According to USDA documents, there are numerous documented cases of inhumane slaughter of horses, ranging from improper handling to outright abuse.

As explained by a USDA inspector working at the Cavel plant in Illinois:

> I observed the plant manager herding horses into the alley way to the knock box. Nine horses were overcrowded in the alleyway causing undue excitement which was further exacerbated when two or 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.

Likewise, on March 13, 2005, a USDA inspector at the Cavel plant reported:

> Eight horses were in the alleyway leading directly to the knock box. The employee who is routinely assigned to work on the kill floor, hanging the horses on the rails, was using a riding crop to whip the horse in the alleyway closest to the knock-box. This horse continued to move backwards, away from the knock-box causing the other horses behind it to be overcrowded. As the whipping continued the horses in the alleyway became extremely excited. I immediately told the employee to stop but he did not listen to me. During this time, the last horse in the alleyway attempted to jump over the alleyway wall and became stuck over the top of the wall. Eventually it had flailed around enough to fall over to the other side of the wall.
>
> * * *
>
> Meanwhile two more horses fell down in the alleyway. The first was the second horse in the line to the knock box. It had fallen forward and the horse behind it began to walk on top of it as the downed horse struggled to get up. The second horse to fall was the fourth horse in the line. It had flipped over backwards due to the overcrowding and was subsequently trapped and trampled by the fifth and sixth horse in the line in their excitement to move forward. Attached to this declaration are true and correct copies of the relevant USDA reports describing these incidents. In my professional opinion, this document illustrates the inhumane treatment of horses.

20. As companion animals, horses are not suited for this kind of inhumane treatment. An alternative for unwanted horses is euthanasia by a trained and licensed veterinarian. As with unwanted dogs and cats, the process of professional euthanasia quickly and painlessly ends the animal's life without the pain and suffering of long-distance transport, handling, and slaughter for human consumption. All equine veterinarians are capable of humanely euthanizing horses. I euthanized horses when I was a large animal practitioner, and it can be done in a quiet, safe and nonfrightening way. The horse does not struggle, is not fearful and dies a quiet and certain death.

21. Horses that eventually make their way to slaughter are taken to large horse auctions where they are purchased by "killer buyers." Some of these horses are healthy retired or unsuccessful race horses. Others are surplus riding school and camp horses. Many were companion animals whose owners gave them up for sale. Wild horses removed from public lands also constitute a percentage of the horses sent for human consumption, as do foals from mares whose urine is collected for the production of hormone replacement therapy drugs.

22. Many of the horses slaughtered are young and healthy, because they have been raised as companion or competitive horses, and treated with all the drugs and substances with which such animals are treated.

23. Many horses who are slaughtered for human consumption are also lame, blind, starved and/or show evidence of lack of care such as saddle sores, overgrown hooves, bad teeth, and injuries. These horses thus also show signs of having been used in the companion and competitive sectors before being sold for meat.

24. In addition, there is believed to be "a thriving trade in stolen horses going to slaughter." C.L. Stull, *Evolution of the Proposed Federal Slaughter Horse Transport Regulations*, 79 J. ANIMAL SCIENCE E12 (2001). The stolen horses presumably come from the sources identified above.

25. Transportation to a slaughter facility, especially in a multiple horse transport

vehicle, is frightening for most horses but is especially traumatic for wild horses, who resist handling during gather and transport operations. 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 high levels of distress and therefore the risk of injury is greater during the events leading up to slaughter.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge, and as to those matters, I believe them to be true.

Executed this 15 day of March, 2012, in Williston, Vt.

Peggy W Larson DVM, MS, JD

Peggy W. Larson, DVM, MS, JD

# EXHIBIT 5

# Residues of Veterinary Medicinal Products - Third Countries

**Imports of animals and their products from third countries:** Provision of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants.



## 1. Background

Article 168 of the Treaty establishing the European Union (EU) states that a high level of human health protection shall be ensured in the definition and implementation of all EU policies and activities. A comprehensive body of EU legislation has been put in place to achieve this objective. All of this legislation is publicly available and can be accessed via the European Commission's EurLex website: http://eur-lex.europa.eu/en/index.htm

With regard to the safety of food, articles 11 to 13 of Regulation 178/2002/EC pdf (Food Law) require that food and feed imported into the EU *"shall comply with the relevant requirements of food law or conditions recognised at least equivalent thereto or, where an agreement exists between the EU and the exporting country, with requirements contained therein".*

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## 2. EU legislation on monitoring of residues and contaminants in food of animal origin.

With regard to residues of veterinary medicines, and some pesticides (dual use substances and organophosphates) and contaminants (heavy metals) in food of animal origin, there is specific EU legislation in place. Council Directive 96/23/EC lays out the requirements that must be met in relation to the planning and execution of national residue control plans for live animals and products of animal origin. The principal objective of the legislation is to detect illegal use of substances in animal production and the misuse of authorised veterinary medicinal products and to ensure the implementation of appropriate actions to minimise recurrence of all such residues in food of animal origin.

Under this legislation Member States are required to submit national residue control plans for approval by the European Commission on an annual basis.

With regard to consignments of food of animal origin imported into the European Union from third countries, samples of these consignments are liable to be taken by the Member States Competent Authorities at Border Inspection Posts (point of entry into the EU) and tested for residues. The conditions of such sampling and testing are described in Commission Regulation (EC) No 136/2004.
Consignments of food which contain residues in excess of EU Maximum Residue Limits - MRLs - (for veterinary medicines), Maximum Residue Levels - MRLs - (for pesticides) and Maximum Limits - MLs - (for contaminants e.g. heavy metals, dioxins etc), or contain residues of substances which do not have an EU MRL or ML may not be legally placed on the EU market and will be rejected. If a particular residue problem is identified, the EU or individual Member States may reinforce checks at the point of import (see Article 24 of Directive 97/78/EC). All reasonable efforts are made to avoid trade disruption. However, in certain cases where there is an evident structural problem in complying with requirements, the European Commission has imposed import bans, pending satisfactory resolution of the problem in the affected third country.

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**3. Residue monitoring: requirements sought from third countries wishing to export food to the EU.**

Residue monitoring requirements for third countries wishing to export food of animal origin to the EU are outlined in Articles 29 and 30 of Council Directive 96/23/EC. Article 29 (1) of the Directive states that a third country must submit a plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC. The guarantees must have an effect at least equivalent to those provided for in the Directive for Member States. The guarantees provided by third countries must, (a) meet the requirements of Article 4 and specify the particulars laid down in Article 7 of this Directive, and (b) meet the requirements of Article 11 (2) of Directive 96/22/EC as amended by Directive 2003/74/EC and Directive 2008/97/EC. A consolidated version of both Directives is available.

The key points are:

- Article 4 of Council Directive 96/23/EC specifies *inter alia* that there must be a centrally co-ordinated residue monitoring plan in place;
- Article 7 (indent 1) of Council Directive 96/23/EC requires a description of the legislation governing the authorisation, distribution and use of veterinary medicinal products;
- Article 7 (indent 6) of Council Directive 96/23/EC states that the number of samples taken should be in accordance with the sampling levels and frequencies laid down in Annex IV to that Directive;
- Article 11 (2) of Council Directive 96/22/EC prohibits Member States from importing from third countries, animals (and/or products derived therefrom) to which stilbenes, thyrostats and estradiol have been administered under any circumstances, or animals (and/or products derived therefrom) to which certain steroid hormones and beta-agonists have been administered for growth *promotion purposes*.

This latter point is particularly important - if a third country authorises the use of hormones and beta-agonists for growth promotion, their residues control plan can only be approved if there is a 'split system' in place, which guarantees that animals (products from which are destined for export to the EU) have not been treated at any time during their rearing.

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**4. The evaluation and approval of residue monitoring plans from third countries:**

Third countries may only be approved for exporting certain food commodities to the EU on submission of a residues monitoring plan, covering each of these food commodities, which has been favourably evaluated by the European Commission services. Plans which are favourably evaluated by the European Commission are *de facto* deemed to offer guarantees equivalent to those provided for by Council Directive 96/23/EC for domestic production. The information from the evaluation is the basis for the formal approval of the plans by means of a Commission Decision. The information is published in Commission Decision 2011/163/EU . Third countries listed in this Commission Decision are eligible to export those commodities for which they are listed to the EU, subject to animal and public health conditions.

It must be emphasised that an approved residue plan is only one of the prerequisites for export to the EU - relevant EU animal and public health conditions must also be satisfied and guidance on this aspect is given on this website at: http://ec.europa.eu/food/international/trade/index_en.htm

**4.1. Timetable for submission of plans and results.**

Third countries are required to submit their residue control plans and results of the previous years exercise to the European Commission by the 31 March each year. The contact details are:

The Director,
Food and Veterinary Office,
Health and Consumer Protection Directorate General,
European Commission,
Grange, Dunsany, Co Meath, IRELAND

Tel: 00353 46 9061833
Fax: 00353 46 9061703
E-mail: SANCO-TCRESIDUEPLANS@ec.europa.eu

**4.2. The evaluation process**

The aim of the evaluation is to assess whether the third country regulatory systems described for the control of residues, authorisation of veterinary medicinal products etc and the plan, offer guarantees which are at least equivalent to those provided for by EU legislation. Sections 5 and 6 of this document explain the features and information which the European Commission services require in order to make such an evaluation. The evaluation exercise recurs annually.

It should be noted that a favourable evaluation is based on the guarantees received on paper. If a subsequent inspection carried out by the FVO, to assess the implementation of residues and veterinary medicines controls, demonstrates that the paper guarantees can not be relied upon, the status of the third country on the list could be revised.

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**5. Key elements required in a residue control plan**

**5.1. The initial plan submitted by a third country must include:**

- information on the structure of the competent authority (central public body) responsible for drawing up the residues control plan and co-ordinating the activities of all subordinate departments playing a role in execution of the plan. The structure and resources of the subordinate bodies needs to be included;
- a description of the legislative framework covering, for example, rules on the use of veterinary medicines and pesticides (organophosphorus compounds and dual use substances), authorisation (and/or prohibition) procedures etc. In particular information on the authorisation/use/prohibition of hormones and beta-agonists for growth promotion and, if authorised, details of particular EU export programmes ('split systems') such as specific programme requirements, advance approval and certification procedures, record keeping requirements, identification systems to distinguish the animals produced under this programme and their food products derived thereof from animals / food produced under the national or other programmes;
- a list of approved laboratories for residues controls and the accreditation status of these laboratories;
- rules covering the collection of official samples;
- details on measures to be taken in the event of an infringement;

**5.2. Subsequent residue control plans**

Third countries are not required to send a detailed description of their regulatory systems every year. Only relevant updates or changes to the system need to be communicated to the European Commission. For a third country with a well established regulatory system, details of which were sent with the initial plan, subsequent communication with the European Commission would normally include:

- the (prospective) residue control plan;
- the results and of the previous year's residue control plan, details on its implementation (i.e. numbers of samples taken compared to the number planned) and the measures taken in the event of non-compliant ('positive') results - this gives the European Commission some indication of how the plan has been implemented and allows the competent authority performance to be evaluated.

However, third countries are welcome to submit all background data (e.g. on the structure of the competent authority, authorisation process for veterinary medicines etc) if they so wish on an annual basis.

**5.3 Importation of horses into the EU and residue requirements.**

Under EU law there are essentially three categories of equidae which are:

- **equidae for slaughter** are defined in Council Directive 90/426/EC as "equidae intended to be transported either directly or after transit through a market or an approved marshalling centre to the slaughterhouse for slaughter".
- **registered equidae** are equidae identified by means of an identification document issued by the breeding authority or any other competent authority of the country where the animal originated, which manages the studbook or register for that breed of animal or, any international association or organisation which manages horses for competition or racing;
- **equidae for breeding and production.** These are all other equidae except those equidae intended for slaughter according to Council Directive 90/426/EC.

***5.3.1. Residue import requirements for equidae***

The ultimate goal of residue-related import requirements is to protect consumers form harmful substances in food. Food obtained from equidae should be safe whether imported (as meat) or whether it is derived from equidae imported and slaughtered in the EU.

***5.3.1.1. Situation in the EU***

In the EU, all equidae have to be accompanied by an identification document (passport) during their movements Commission Regulation (EC) No 504/2008. This provision has amongst others been introduced for the protection of consumers against harmful residues in food obtained from equidae treated with pharmacologically active substances.

There is a new Regulation of the European Parliament and of the Council laying down EU procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (Regulation (EC) No 470/2009 pdf ). Under this Regulation substances for which a full EU evaluation has been possible are listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010 pdf . In the EU, equidae may be treated with such substances and, provided that appropriate medicine withdrawal periods are met prior to slaughter, the meat from such animals may enter the food chain. Such treatments must be recorded in a medicines record kept on the farm as required by Article 10 of Council Directive 96/23/EC pdf and Annex I, Part A, III, point 8(b) to Regulation (EC) No 852/2004 pdf .

A full EU evaluation has not been possible for certain substances deemed essential for the treatment of equidae. These are listed in Commission Regulation (EC) No 1950/2006 pdf but as they have not been fully assessed are therefore **excluded** from Table 1 in the Annex to Commission Regulation (EU) No 37/2010 pdf . In the EU treatments of equidae with such substances is possible provided that it is documented in the equine passport and that a default withdrawal period of six months is observed. It should be noted that some medicines commonly used in horses world-wide such as phenylbutazone are neither listed in Commission Regulation (EC) No 1950/2006 pdf or in Table 1 in the Annex to Commission Regulation (EU) No 37/2010 pdf . Any horse in the EU treated with phenylbutazone must be excluded from the food chain and be signed out of the food chain in the equine passport.

In the EU horses which are intended for food production may **not** be treated with substances for which it has not been possible to establish an MRL. Such substances which include chloramphenicol, nitrofurans and nitroimidazoles are listed in Table 2 in the Annex to Commission Regulation (EU) No 37/2010 pdf . If horses have been treated with any of these substances, the animals must be signed out of the food chain and this exclusion has to be documented in the equine passport which accompanies the animal to the slaughterhouse. Furthermore in the EU horses intended for food production may neither be treated with hormonal steroids for growth promotion purposes nor with certain anabolic or gestagenic steroids for therapeutic and/or zootechnical purposes as specified in Council Directive 96/22/EC pdf .

#### *5.3.1.2. Requirements for third countries*

Third countries which are exporting meat derived from equidae are obliged to implement a residue control plan which satisfies the requirements of Council Directive 96/23/EC. For equidae caught in the wild, the provisions as laid down for wild land mammals apply. These provisions foresee the submission of an annual residue monitoring plan which is restricted to the analysis of environmental contaminants (e.g. heavy metals). Countries so approved will be listed in the Annex to Commission Decision 2004/432/EC under the column entitled "Equine".

Live equidae exported to the EU for food production (i.e. slaughter) can only be permitted from a third country which has implemented a residue plan giving guarantees equivalent to those required by Council Directive 96/23/EC. Countries so approved will also be listed in the Annex to Commission Decision 2004/432/EC under the column entitled "Equine" with a supplementary footnote "Exports of live equidae for slaughter (food producing animals only)".

If equidae in third countries have been treated with either:

(a) substances listed in Table 2 in the Annex to Commission Regulation (EU) No 37/2010 pdf (e.g. chloramphenicol, nitrofurans or nitroimidazoles etc) *or*;

(b) hormonal steroids for growth promotion purposes *or*;

(c) *certain* anabolic or gestagenic steroids for therapeutic and/or zootechnical purposes as specified in Council Directive 96/22/EC pdf ;

**these animals may not be exported for direct slaughter in the EU and meat from these animals is not eligible for export to the EU and should be entirely excluded from the food chain.**

Taking into consideration that in most cases horses are not specifically reared as food producing animals and usually end up in the food chain at the end of their productive lives, special attention needs to be given to the requirements of Council Directives 96/23/EC and 96/22/EC which should guarantee that the horses slaughtered are safe for human consumption. Notwithstanding third countries' existing obligations to implement a residue monitoring plan and submit this on an annual basis to the Commission services for approval, third countries are expected to implement the following measures for those

equidae, meat from which is intended to be exported to the EU:

- Equine animals intended for food production should be identified and a system of identity verification should be established.
- In third countries where anabolic steroids are marketed for fattening purposes, there should either be a prohibition on the administration of anabolic steroids for growth promotion purposes to all equidae or there should be a separate system for equidae which may be slaughtered for export of equine meat to the EU. This would require that equidae intended for meat production for the EU would be identified and segregated from those equidae treated with anabolic steroids.
- Treatment records. The purpose of recording treatments of animals with veterinary medicinal products is to ensure that animals are not slaughtered within the withdrawal period of the medicine in question, thus providing guarantees that the EU Maximum Residue Limit (MRL) for the particular pharmacologically active substance is respected. In the EU stock farmers are required to keep medicines records. On that basis it is expected that treatments with veterinary medicinal products should be recorded on a document linked to and accompanying the identified animal when moving from one premise to another or to the slaughterhouse (food chain information).
- At the time of moving the animal to the slaughterhouse, the competent authority of the third country should be able to guarantee that the required withdrawal periods for veterinary medicinal products administered to the animal and recorded in the food chain information have been respected.
- The third-country exporting equine meat should set up a risk based programme for controls on the use of veterinary medicinal products and substances prohibited for use in the EU. The control programme should include regular inspections on holdings, collection centres and at slaughterhouses.

In order for the Commission services to be able to assess the implementation of these measures, third countries intending to export equine meat to the EU **must submit an action plan to the FVO in conjunction with the residue control programme**. Annual updates on these action plans should be submitted along side the residue control plans and results of monitoring.

This action plan should describe how the minimum set of measures referred to above will be implemented and the timelines for so doing. All of these measures should be in place by **31 July 2010**. At that time, only horses with a known medicinal treatment history, and which on the basis of medicinal treatment records can be shown to have satisfied the appropriate veterinary medicine withdrawal periods, should be allowed to be slaughtered for export to the EU. Where appropriate, the implementation of these action plans may be inspected on the spot by the FVO.

In 2010 the EU will reconsider the abovementioned measures and, if appropriate, make the necessary amendments in order to continue ensuring that food safety standards applied in exporting third countries give guarantees equivalent to those foreseen by EU legislation.

**Situation regarding 'Registered' equidae**

Imports of registered equidae or equidae for breeding and production, under the conditions of Decision 93/197/EEC **and** for which the customs procedures have been completed cannot be slaughtered in the EU for food production before they have received an EU-conforming passport.

Registered equidae temporarily admitted into the EU according to Decision 92/260/EEC cannot be slaughtered for food production in the EU.

The table below summarises the legal position for each type of importation of equidae.

| Importing Legislation | Description | Need for a residue plan in the exporting third country | Can these animals be slaughtered in the EU |
|---|---|---|---|
| Council Directive 90/426/EEC | Import for **slaughter** | Yes | Yes - immediate |
| Commission Decision 93/197/EEC | Import of registered equidae or equidae for | No | Yes, but only on condition that an EU passport has been issued and |

| | | | |
|---|---|---|---|
| | breeding and production | | possibly only after a defined period. |
| Commission Decision 92/260/EEC | Temporary admission | No | No |

**5.4. Exemption for third countries exporting casings only**

Natural casings are membranous cases made of animal intestine which are used to contain sausage or other processed meat. Third countries exporting casings (but no other meat products from that species) to the EU may export these casings without the need for submitting a specific residue control plan for casings to the Commission services. In the latest revision to Commission Decision 2004/432/EC (Commission Decision 2007/115/EC) there is no longer any specific list of third countries authorised to export casings only to the EU i.e. the footnote "approved for import of animal casings", no longer exists.

For completeness, it is reiterated that intestines of bovine animals (cattle) of all ages and the ileum of ovine (sheep) and caprine animals (goats) of all ages are considered a 'specified risk material as regards the transmission of BSE (Bovine Spongiform Encephalopathy). Therefore exports of natural casings derived from cattle, sheep and goats to the EU are only authorised from those third countries where the BSE risk is highly unlikely. These 'low risk' countries are listed under point 15 (b) of Annex XI to Regulation (EC) No 999/2001. Legislation on Regulation (EC) No 999.2001 (TSE - consolidated) pdf

For those third countries which are seeking to export both casings and meat or other animal products, a residue monitoring plan must be in place for the relevant species.

**5.5. Residues in honey**

Honey is defined in Council Directive 2001/110/EC. In contrast to many food commodities, there are relatively few EU Maximum Residue Limits (MRLs) established for residues of pharmacologically active substances in honey (e.g. tau-fluvalinate and amitraz). In particular antimicrobial/antibiotic drugs are not authorised for the treatment of honey bees in the EU because there are no EU MRLs. However, it is certainly the cas e that antimicrobial drugs are authorised for the treatment of honey bees in many third countries.

This situation may potentially raise some problems with imports of honey into the EU. In the absence of EU MRLs, the presence of any detectable residues in honey imported into the EU would mean that those consignments can not legally be placed on the market in the EU. **Therefore it is important that analytical methods used in third countries' residue control plans are as sensitive and reliable as possible in order to provide assurances that honey exported from third countries to the EU will comply with EU rules**.

EU rules on setting of MRLs for pharmacologically active substances have been updated by Regulation (EC) No 470/2009. This legislation has, for the first time, introduced a mechanism for the extrapolation of MRLs from one species/food commodity to another. In addition the legislation elaborates the principles by which the European Commission can establish so-called "Reference Points for Action" (RPAs) for residues of pharmacologically active substances for which MRLs have not been (nor can not be) established. **It is important to stress that RPAs are NOT MRLs**. RPAs are residue concentrations which are technically feasible to detect by food control laboratories. In the event that the RPA is exceeded, the Member State is obliged to reject the consignment as it can not be legally placed on the EU market (see Article 23 of Regulation (EC) No 470/2009).

If a food control laboratory in an EU Member State unequivocally confirms and quantifies the presence of a substance at a concentration below the RPA (where an RPA has been established) in an imported consignment (i.e. the decision limit CCα as defined in Article 6 of Commission Decision 2002/657/EC has been exceeded), the Member State competent authority is obliged to permit the consignment to be placed on the market, however, it is also obliged to follow certain administrative procedures including, in some circumstances, informing the Commission services.

The RPA concept is not new – it has been described in Commission Decision 2005/34/EC and to date RPAs have been established in honey for substances such as chloramphenicol and nitrofurans. **It is important to stress that in the absence of either MRLs or RPAs for many residues of pharmacologically active substances in honey, the finding**

**of any confirmed residue concentration in honey shall result in the rejection of the consignment.**

**5.6. Structure of the residue control plan**

In order to clarify precisely what the European Commission expects third countries to include in their residue control plans, and to facilitate harmonisation of the format in which such plans should be submitted, a number of documents and pro-forma tables are appended which may be used for constructing the plan. These are described in more detail in section 6.

***5.6.1. Coverage of the plan - what commodities have to be included:***

Only those commodities which are currently being exported to the EU (or which the third country wishes to export to the EU) need to be included in the plan.

***5.6.2. Sampling levels and frequencies***

Sampling levels and frequencies are laid down in Council Directive 96/23/EC and Commission Decision 97/747/EC. They are based on annual national production figures. Every EU Member State is obliged to observe these sampling levels and the relevant information is included in this file: Sampling levels and frequencies

For third countries, the number of samples to be taken depends on the structure of the relevant industry. For example in the case of those third countries where animals and products from any farm are eligible to be exported to the EU, the proportion of animals sampled should be taken relative to the annual national production figures i.e. in line with the sampling levels and frequencies used by the Member States. Briefly, the sampling requirements are as follows:

| Species | Commodity | Frequency |
|---|---|---|
| Bovine | Meat | 0.4 % of the animals slaughtered the previous year |
| Bovine / Ovine / Caprine | Milk | One per 15000 tonnes of annual production - minimum 300 samples |
| Porcine | Meat | 0.05 % of the animals slaughtered the previous year |
| Caprine, ovine | Meat | 0.05 % of the animals slaughtered the previous year |
| Equine | Meat | No frequency or minimum number of samples established |
| Poultry | Meat | One per 200 tonnes of annual production (deadweight) |
| | Eggs | One per 1000 tonnes of annual production for human consumption - minimum 200 samples |
| Rabbit | Meat | 10 per 300 tonnes of annual production (deadweight) for the first 3000 tonnes + 1 sample for every 300 tonnes thereafter |
| Farmed & wild game | Meat | At least 100 samples |
| Farmed fin fish | Meat | One per 100 tonnes of annual production (deadweight) |
| Bees | Honey | 10 per 300 tonnes of annual production for human consumption for the first 3000 tonnes + 1 sample for every 300 tonnes thereafter |

However, for those countries where only a defined population of animals are eligible for export to the EU, and where there is a system in place guaranteeing that only those animals from those farms are eligible for export, it is permissible that the proportion of animals sampled is relative to that defined population rather than the national population. Each sample can be analysed for detecting the presence of one or more substances within a substance group. The use of multi-residue analytical methods is to be encouraged.

***5.6.3. Selection of residues to be included in the residue control plan.***

Council Directive 96/23/EC, requires that third countries must be able to provide guarantees on the residue status of exported product with respect to all of the specified substance groups listed in Annex I to that Directive. The substance groups are classified in two main categories - Group A and Group B. Group A contains most of the substances which are prohibited from use in food producing animals in the EU and the Group is subdivided into 6 subgroups (A1-A6). Group B contains residues of many pharmacologically active substances which may be authorised for use in food producing animals in the EU (i.e. are listed in Annex I to III to Council Regulation (EEC) No 2377/90). It also comprises organochlorine and organophosphate pesticides and also chemical elements such as lead, cadmium and mercury.

Annex II to Council Directive 96/23/EC lists for each commodity (e.g. bovine animals, milk, eggs etc) which Group A and Group B subgroups must be monitored for in the respective commodities. Although Member States are obliged to follow these rules, there is some flexibility in the case of third countries.

Those substance groups classified in Group A are of greatest concern to the EU as their use is either entirely prohibited or firmly restricted are. Consequently, third countries are advised that, in respect of compounds in Group A1, A2, A3, A4, A5 and A6, these must be monitored for in the relevant commodities. The absence of testing could result in the residue plan not being approved and the third country would therefore be ineligible to export those commodities.

There are several *other* substances banned from use in animal production in the EU which are *not* currently listed in Group A. Examples include malachite green (which has been used for the treatment of fungal disease in fish) and several growth promoting antibiotic substances which have been expressly prohibited for inclusion in animal feedingstuffs in the EU because of identified chemical risks (e.g. olaquindox and carbadox and the nitrofuran, nifursol ). Data on all of these substances were examined by an independent scientific committee which provided advice to the European Commission. The assessments for nifursol , carbadox and olaquindox are available here.

In the interests of harmonising the analytical capability of Member State laboratories testing for residues of these substances in food of animal origin, the European Commission services are in the process of establishing minimum required performance limits (MRPLs) for olaquindox and carbadox residues - MRPLs have already been established for residues of several 'banned' substances including the nitrofurans and malachite green - see section 5.5.4. below.

If the use of such substances is authorised in a third country, particular in livestock production destined for the EU market, the country should consider analytical and/or other control strategies which will provide equivalent guarantees to those provided for by current EU legislation. Such strategies should result in the European consumer being protected from exposure to the presence of residues in food of animal origin

exported to the EU - the same objective achieved by the ban on use within the EU.

In respect of the Group B substances, third countries should test for those substances which are likely to be used in their livestock production systems. They should justify their choice of substances tested with a documented risk-based approach. If there are substance-sub-groups listed in Group B which are *not* tested for in their plans, such omissions would have to be justified and supported by appropriate documentary evidence submitted with the plan. Such evidence could consist of one or more of the following:

- a register of authorised medicines (and chemical class) for use in each species of food producing animal;
- historical residue monitoring data justifying any decisions not to include specific substance groups in the monitoring plan etc;
- toxicological data or preferably an assessment of the chemical risk of individual compounds, the use patterns of these compounds in each of the (export) livestock sectors, the likelihood of potentially harmful residues occurring and the relative risk of consumers being exposed to such residues.

Those third countries electing to implement in their national provisions measures fully equivalent to Council Directive 96/23/EC in full (as all EU Member States are obliged to do) would not be obliged to provide information on (2) and (3) above. Third countries following the residue monitoring approach advocated by the Codex Alimentarius /download/standards/11252/CXG_071e.pdf pdf would have to justify (on the basis of risk) the absence of monitoring of any Group B substances which are listed in Council Directive 96/23/EC.

Table 2 pdf lists the substance groups that should be monitored for each animal species or product. Substances or groups of substances which are of particular concern for the EU and for which monitoring is therefore expected, are detailed and highlighted by means of the letter "E" (essential) in the corresponding cell. The same is done for substances which are frequently detected in the different commodities and therefore should be included in the programme. Other substances or groups of substances to be tested in the different commodities are highlighted by means of the letters "HD" (highly desirable). Decisions to *omit* HD substances/substance groups from the plan should be justified and supported by appropriate documentary evidence. The list of individual substances in this table is not exhaustive. If on the basis of a risk assessment, third countries wish to test for additional substances, they are encouraged to so.

***5.6.4. Maximum Residue Limits and 'action levels' in food of animal origin.***

Regulation (EC) No 470/2009 pdf of the European Parliament and of the Council lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food of animal origin. A complete list of pharmacologically active substances and their MRLs is available in the Annex to Commission Regulation (EU) No 37/2010 pdf . EU Maximum Residue Levels have been established for a wide range of pesticides by Regulation (EC) No 396/2005. These are laid down in various Commission Regulations and may be accessed via the Commission's on-line database of pesticides accessible here. Maximum Levels for certain environmental contaminants are laid down in Commission Regulation (EC) 1881/2006.

In the case of coccidiostats and histomonostats, some of these are 'dual-use' substances i.e. have been authorised either as veterinary medicinal products and/or as feed additives. A Community Register of Feed Additives has been established and the coccidiostats and histomonostats so authorised include decoquinate, robenidine, halofuginone, diclazuril and the ionophores monensin, salinomycin, maduramycin, semduramycin, lasalocid, narasin and narasin combined with nicarbazin.

When an MRL for the substance concerned has already been established for that substance when used in a veterinary medicinal product, that MRL shall also apply to residues originating from the use of the same substance as a feed additive. Consequently the MRLs established for decoquinate, halofuginone, lasalocid and monensin as veterinary medicinal products under Regulation (EC) No 470/2009 pdf and listed in the Annex to Commission Regulation (EU) No 37/2010 pdf apply if those substances are used as feed additives in the species for which the MRL has already been set.

For those coccidiostats and histomonostats which are not authorised for use as veterinary medicinal products, but only as feed additives, MRLs have been established for individual formulations of each of these feed additives. For example, in the case of monensin, Coxidin (a formulation of monensin sodium authorised as a feed additive for chicken and turkeys), MRLs have been set in chicken and turkey tissues by Commission Regulation (EC) No 156/2008 pdf .

It has also been recognised that unavoidable cross contamination of animal feedingstuffs can occur with these additives

(i.e. trace quantities can end up in feed intended for other species) and give rise to residues in food derived from those animals. Commission Regulation (EC) No 124/2009 pdf lays down maximum levels for the presence of coccidiostats or histomonostats in food derived from these so-called 'non-target' species which have resulted from the unavoidable carry-over of these substances into animal feedingstuffs.

For several substances which have been expressly prohibited from use in food producing animals in the EU (e.g. chloramphenicol, nitrofurans), or not authorised (e.g. malachite green), the concept of the minimum required performance limit (MRPL) has been established in Commission Decision 2002/657/EC.

MRPLs are defined as *"minimum content of an analyte in a sample, which at least has to be detected and confirmed"* and are the reference point for action in relation to the evaluation of consignments of food ( Commission Decision 2005/34/EC pdf ). To date MRPLs have been established for the following substances:

| Substance and/or metabolite | Matrices | MRPL | Reference |
|---|---|---|---|
| Chloramphenicol | Meat, Eggs, Milk, Urine, Honey<br><br>Aquaculture products | 0,3 µg/kg | Commission Decision 2003/181/EC |
| Medroxyprogesterone acetate | Pig kidney fat | 1 µg/kg | |
| Nitrofuran metabolites*:<br><br>- furazolidone<br><br>- furaltadone<br><br>- nitrofurantoin<br><br>- nitrofurazone | Poultry meat for all<br><br>Aquaculture products | 1 µg/kg | |
| Sum of malachite green and leucomalachite green | Meat of aquaculture products | 2 µg/kg | Commission Decision 2004/25/EC pdf |

With regard to each of these EU limits/levels, Member States are required to ensure that they have validated laboratory analytical methods in place which are capable of meeting these thresholds.

In the context of providing guarantees on the residue status of commodities exported to the EU, third countries should also be able to demonstrate that the analytical methods used in their national residue control plans are validated and can meet these levels/limits.

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**6. General instructions and pro formas for submission plans and results.**

The following instructions and pro forma tables provide for all of the necessary information which the European Commission needs in order to evaluate whether the third country residue control plan can offer guarantees equivalent to those provided for by EU legislation.

All of the elements and information which the European EU expects from a third country submitting a residues control plan are summarised in Table 1 (Updated 20-03-2008) which is laid out as a form for completion by the Competent Authority. The table is divided into four main sections - the competent authority, the residue control plan, the laboratory network and the authorisation and control of veterinary medicines. In each of these sections more detailed information is required.

Table 2 (Updated 11/10/2006) summarises all of the substances or groups of substances that should be monitored for each animal species or product.

The sampling levels and frequencies are described for each commodity in: Sampling levels and frequencies .

The Plan Template (Updated 06/10/2009) can be used to enter the production data for each commodity. The minimum numbers of samples required under EU rules are automatically updated. Details of the analytes, materials to be tested, screening and confirmatory analytical methods etc can be entered. An An example of a completed specimen plan for aquaculture products (finfish and shrimp) is included for information for aquaculture products (finfish) is included for information. The list of substances used by all of the Member States Substances is included for reference. This indicates the Group (relative to Annex I to Council Directive 96/23/EC) and the Chemical Abstracts Service (CAS) number for the compounds.

Finally the Tables of results (Updated 22/02/2007) for each commodity have been prepared in order to facilitate the uniform presentation of results of residue monitoring for all third countries. A distinct table can be filled in for each commodity.

**Links included in the document**

Provision of guarantees equivalent to EU requirements on residues of veterinary medicines, pesticides and contaminants.
http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm
Background
http://ec.europa.eu/food/food/chemicalsafety/residues/#1
EU legislation on monitoring of residues and contaminants in food of animal origin.
http://ec.europa.eu/food/food/chemicalsafety/residues/#2
Residue monitoring: requirements sought from third countries wishing to export food to the EU
http://ec.europa.eu/food/food/chemicalsafety/residues/#3
The evaluation and approval of residue monitoring plans from third countries:
http://ec.europa.eu/food/food/chemicalsafety/residues/#4
Timetable for submission of plans and results
http://ec.europa.eu/food/food/chemicalsafety/residues/#4.1
The evaluation process
http://ec.europa.eu/food/food/chemicalsafety/residues/#4.2
Key elements required in a residue control plan:
http://ec.europa.eu/food/food/chemicalsafety/residues/#5
The initial plan submitted by a third country must include
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.1
Subsequent residue control plans
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.2
Importation of horses into the EU and residue requirements
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3
Residue import requirements for equidae
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3.1
Situation in the EU
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3.1.1
Requirements for third countries
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.3.1.2
Exemption for third countries exporting casings only
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.4
Residues in honey
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.5
Structure of the residue control plan:
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6

Coverage of the plan - what commodities have to be included
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.1
Sampling levels and frequencies
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.2
Selection of residues to be included in the residue control plan
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.3
Maximum Residue Limits and 'action levels' in food of animal origin
http://ec.europa.eu/food/food/chemicalsafety/residues/#5.6.4
General instructions and pro formas for submission plans and results
http://ec.europa.eu/food/food/chemicalsafety/residues/#6
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://eur-lex.europa.eu/en/index.htm
http://eur-lex.europa.eu/en/index.htm
Regulation 178/2002/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT
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http://ec.europa.eu/food/food/chemicalsafety/residues/
Council Directive 96/23/EC
http://ec.europa.eu/food/food/chemicalsafety/residues/council_directive_96_23ec.pdf
Commission Regulation (EC) No 136/2004
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004R0136:EN:NOT
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Directive 96/22/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31996L0022:EN:NOT
Directive 2003/74/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003L0074:EN:NOT
Directive 2008/97/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008L0097:EN:NOT
consolidated version
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01996L0022-20081218:EN:NOT
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Commission Decision 2011/163/EU
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:070:0040:0046:EN:PDF
http://ec.europa.eu/food/international/trade/index_en.htm
http://ec.europa.eu/food/international/trade/index_en.htm
http://ec.europa.eu/food/food/chemicalsafety/residues/
SANCO-TCRESIDUEPLANS@ec.europa.eu
http://ec.europa.eu/food/food/chemicalsafety/residues/mailto:SANCO-TCRESIDUEPLANS@ec.europa.eu
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http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
Council Directive 90/426/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01990L0426-20080903:EN:NOT
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Regulation (EC) No 504/2008
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R0504:EN:NOT
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Council Directive 96/23/EC
http://ec.europa.eu/food/food/chemicalsafety/residues/council_directive_96_23ec.pdf
Regulation (EC) No 852/2004
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0003:0021:EN:PDF
Commission Regulation (EC) No 1950/2006
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:367:0033:0045:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF

Commission Regulation (EC) No 1950/2006
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:367:0033:0045:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Council Directive 96/22/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0022:20081218:EN:PDF
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Council Directive 96/22/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1996L0022:20081218:EN:PDF
Decision 93/197/EEC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01993D0197-20070101:EN:NOT
Decision 92/260/EEC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:01992D0260-20070101:EN:NOT
http://ec.europa.eu/food/food/chemicalsafety/residues/
Legislation on Regulation (EC) No 999.2001 (TSE - consolidated)
http://ec.europa.eu/food/food/chemicalsafety/residues/reg_999_2001_tse_consolidated_en.pdf
http://ec.europa.eu/food/food/chemicalsafety/residues/
Council Directive 2001/110/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:010:0047:0052:EN:PDF
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Decision 2002/657/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:221:0008:0036:EN:PDF
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
http://ec.europa.eu/food/food/chemicalsafety/residues/
Commission Decision 97/747/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997D0747:EN:NOT
Sampling levels and frequencies
http://ec.europa.eu/food/food/chemicalsafety/residues/sampling_levels_frequencies_jme.doc
http://ec.europa.eu/food/food/chemicalsafety/residues/
olaquindox
http://eurlex.europa.eu/pri/en/oj/dat/1998/l_347/l_34719981223en00310032.pdf
carbadox
http://eurlex.europa.eu/pri/en/oj/dat/1998/l_347/l_34719981223en00310032.pdf
nifursol
http://eurlex.europa.eu/pri/en/oj/dat/2002/l_265/l_26520021003en00010002.pdf
nifursol
http://ec.europa.eu/food/fs/sc/scan/out119_en.pdf
carbadox and olaquindox
http://ec.europa.eu/food/fs/sc/scan/out13_en.pdf
/download/standards/11252/CXG_071e.pdf
http://www.codexalimentarius.net/download/standards/11252/CXG_071e.pdf
Table 2
http://ec.europa.eu/food/food/chemicalsafety/residues/table2_101106.pdf
http://ec.europa.eu/food/food/chemicalsafety/residues/
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Regulation (EC) No 396/2005
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:02005R0396-20080410:EN:NOT
here
http://ec.europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm
Commission Regulation (EC) 1881/2006
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1881:EN:NOT
Community Register of Feed Additives
http://ec.europa.eu/food/food/animalnutrition/feedadditives/registeradditives_en.htm
Regulation (EC) No 470/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0011:0022:EN:PDF
Commission Regulation (EU) No 37/2010
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF
Commission Regulation (EC) No 156/2008
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:048:0014:0015:EN:PDF

Commission Regulation (EC) No 124/2009
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:040:0007:0011:EN:PDF
Commission Decision 2002/657/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002D0657:EN:NOT
Commission Decision 2005/34/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0034:EN:NOT
Commission Decision 2003/181/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0181:EN:NOT
2004/25/EC
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Table 1 (Updated 20-03-2008)
http://ec.europa.eu/food/food/chemicalsafety/residues/table1.doc
Table 2
http://ec.europa.eu/food/food/chemicalsafety/residues/table2_101106.pdf
Sampling levels and frequencies
http://ec.europa.eu/food/food/chemicalsafety/residues/sampling_levels_frequencies_jme.pdf
Plan Template
http://ec.europa.eu/food/food/chemicalsafety/residues/plantemplate.xls
An example of a completed specimen plan for aquaculture products (finfish and shrimp) is included for information
http://ec.europa.eu/food/food/chemicalsafety/residues/plan_template_specimen_en.pdf
Substances
http://ec.europa.eu/food/food/chemicalsafety/residues/substances_jme.doc
Tables of results (Updated 22/02/2007)
http://ec.europa.eu/food/food/chemicalsafety/residues/resultstemplate.xls

# EXHIBIT 6

## DECLARATION OF HILARY WOOD

I, Hilary Wood, declare as follows:

1. I am the President and Founder of Front Range Equine Rescue ("FRER"), a 501(c)(3) nonprofit organization incorporated in Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection. If called, I could and would testify to these facts in a court of law.

2. 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. 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. FRER has assisted thousands of horses through its rescue and educational programs. While some of FRER's horses are surrendered by their owners or rescued when abandoned, many are rescued from livestock auctions; others are purchased at feed lots before they are sent to slaughter.

3. FRER directly rescues approximately 100 – 120 new horses per year. FRER horses live at facilities owned by FRER, at private foster homes, or at other privately contracted facilities.

4. One of FRER's primary goals is to purchase horses destined for slaughter for human consumption. Once rescued, FRER provides for the direct care and rehabilitation of these horses, provides training assessment, and then adoption into permanent and suitable homes for them.

5. I have personally been housing and providing for the care of horses for over twenty years.

6. In connection with my work with FRER and my own personal ownership of horses, I have become intimately familiar with the drugs, treatments and substances used by horse owners in America.

7. I assisted in the preparation of and have reviewed Exhibit 1 to the Petition for Rulemaking being submitted by FRER. Every item on that list is either commonly found in barns housing horses, and is used on those horses, or is found in catalogues and supply stores, for sale to private horse owners in America or available with a veterinarian's prescription. I am personally familiar with and use or have used at least 50 of the substances on that list, and am informed and believe that all of those substances are used regularly on companion, pleasure and recreation, and competition/show horses.

8. FRER has rescued horses from auction lots who were born as wild horses, captured by the federal Bureau of Land Management ("BLM"), and eventually ended up for sale. I have also directly adopted wild horses from the BLM. Records that accompanied these horses showed that they received some of the drugs on Exhibit 1, including but not limited to a series of vaccinations for many diseases, dewormers, which are labeled as prohibited for use in animals which will be eaten.

9. As part of FRER's mission, I have participated in the purchase of slaughter-bound horses directly from lots that were the horses' last stop before slaughter. Many of those horses, who would have entered the slaughter process otherwise, were sick with contagious respiratory illnesses. Many others developed serious illnesses, such as *Streptococcus equi* ("strangles"), a virulent and highly contagious equine infection, within a week of our acquisition.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 19th day of March, 2012, in Larkspur, Colorado.

Hilary Wood

# EXHIBIT 7

## DECLARATION OF JOANNE PAVLIS

I, Joanne Pavlis, declare as follows:

1. I am a professional horse trainer with Milemakers, LLC of Larkspur, Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. Milemakers LLC provides training for horses and specializes in the education, training and condition of Endurance and Pleasures Distance horses and riders. We also provide conditioning for Arabian race horses who will be used on the racetrack, a beginning program for junior riders, and coaching for trail rides.

3. I have been training horses for eighteen years and have worked as a trainer with Milemakers for the last sixteen years. In the course of my work I have seen hundreds of horses, gotten to know hundreds of their owners, and am familiar with the drugs, treatments and substances used by owners of companion horses, sporting and competitive horses, and horses destined for racing.

4. I have reviewed Exhibit A to the Petition for Rulemaking being submitted by Front Range Equine Rescue. I am familiar with virtually all the drugs, treatments and substances listed on Exhibit A.

5. The drugs, treatments and substances listed on Exhibit A are all very commonly used by owners of companion horses and competition horses. Virtually all such owners would either have these drugs, treatments and substances on hand and use them on their horses, or would have access to the drugs treatments and substances, and be able to easily get them from their local veterinarian.

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// JP

6. I am also familiar with and have had experience with wild horses who have been captured and placed in holding pens. These horses are given some of the drugs, substances and treatments on Exhibit A, including many commonly-used veterinary drugs.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 19 day of March, 2012, in Larkspur, Colorado.

Joanne Pavlis

# EXHIBIT 8

## DECLARATION OF RANDY PARKER, D.V.M.

I, Randy Parker, declare as follows:

1. I am a veterinarian and own and manage Range View Equine Associates in Elbert, Colorado. I have personal knowledge of the facts set forth in this declaration. The facts set forth are true to the best of my knowledge and recollection.

2. I am a 1989 graduate of Tufts University School of Veterinary Medicine, and have been practicing veterinary medicine for twenty-three years. After graduation from Tufts, I did an internship on Prince Edward Island, focusing on large animal, food animal and equine practice.

3. After my internship I moved to Colorado where I have been in practice ever since. My veterinary practice focuses almost exclusively (greater than ninety percent) on the care of companion horses, and horses used in competition, show and sporting events.

4. I see an average of thirty horses every week as part of my practice.

5. In the course of my practice I prescribe medications needed by the horses I treat. I also visit the barns, tack rooms, and treatment areas in which my clients' horses live, and regularly observe the kinds of drugs, substances, and treatments my clients use for their horses, whether prescribed or acquired elsewhere.

6. I have reviewed Exhibit 1 to the Petition for Rulemaking submitted by Front Range Equine Rescue. I am familiar with the large majority of the drugs, treatments and other substances on Exhibit 1, which I have either prescribed myself or seen at the barns of and in use by my clients for their horses.

7. Many of the drugs on this list are harmful to humans. For example, chloramphenicol is known to cause aplastic anemia and other problems. Nitrofurazone, which is commonly used, is a human carcinogen. Additionally, the administration of any antibiotic to horses, if those horses were then eaten, could lead to the development of antibiotic resistances in humans.

8. The majority of drugs, treatments and substances on Exhibit 1 to the Petition are regularly and routinely used by owners of horses in the areas where I work, and I believe this practice to be common throughout the country.

9. Based on my training and experience, it is my professional opinion that an alarming majority of American horses who are sent to slaughter for human consumption may have been treated with a variety of drugs, treatments and substances that renders their flesh dangerous to people who eat horse meat and makes the horses' meat unsafe for human consumption.

I declare under penalty of perjury that the foregoing is true and correct, based on my own personal knowledge and experience.

Executed this 17 day of March, 2012, in Elbert, CO

Randy Parker, D.V.M.

# EXHIBIT 9

## Inspections, Compliance, Enforcement, and Criminal Investigations

### Snellman Farms 6/1/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

June 1, 2012

**WARNING LETTER CIN-12-302058-21**

**Hand Delivered**

Mr. Peter Snellman, Owner
Snellman Farms
8151 State Route 669 Northwest
McConnelsville, Ohio 43756

Dear Mr. Snellman:

On March 6, 7, and 9, 2012, the U.S. Food and Drug Administration (FDA) conducted an investigation of your veal calf growing operation located at 8151 State Route 669 NW, McConnelsville, Ohio. This letter notifies you of the violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that we found during our investigation of your operation. You can find the FD&C Act and its associated regulations on the internet through links on FDA's web page at www.fda.gov[1].

We found that you offered for sale an animal for slaughter as food that was adulterated. Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. 360b. Further, under section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4), a food is deemed to be adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health.

Specifically, our investigation revealed that on or about **(b)(4)**, you hauled **(b)(4)** calves to **(b)(4)**, for slaughter as food. On or about **(b)(4)** slaughtered these animals. United States Department of Agriculture, Food Safety and Inspection Service (USDA/FSIS) analysis of tissue samples collected from **(b)(4)** of the **(b)(4)** calves identified the presence florfenicol at 0.50 parts per million (ppm) in the liver of this animal. FDA has established a tolerance of 3.7 ppm for residues of florfenicol in the liver tissue of cattle as codified in Title 21, **Code of Federal**

**Regulations**, Part 556.283 (21 C.F.R. 556.283). However, this tolerance does not apply to residues of florfenicol in calves to be processed for veal. As such, there is no acceptable level of residue associated with florfenicol in calves to be processed for veal. The presence of this drug in edible tissue from this animal in any amount causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to maintain complete treatment records. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the FD&C Act, 21 U.S.C. § 342(a)(4).

We also found that you adulterated the drug **(b)(4)**. Specifically, our investigation revealed that you did not use **(b)(4)**, as directed by its approved labeling and your servicing veterinarian's written prescription. Use of this drug in this manner is an extralabel use. See 21 C.F.R. 530.3(a).

The extralabel use of approved animal or human drugs in animals is allowed under the FD&C Act only if the extralabel use complies with sections 512(a)(4) and (5) of the FD&C Act, 21 U.S.C. § 360b(a)(4) and (5), and 21 C.F.R. Part 530, including that the use must be by or on the order of a licensed veterinarian within the context of a veterinarian/client/patient relationship.

Our investigation found that you administered the new animal drug **(b)(4)**, to your calves to be processed for veal without following the animal class as stated in the approved labeling or the withdrawal period established by your servicing veterinarian. Your extralabel use of the new animal drug **(b)(4)**, was not under the supervision of a licensed veterinarian, in violation of 21 C.F.R. 530.11(a) and resulted in an illegal residue, in violation of 21 C.F.R. 530.11(c). Because your use of this drug was not in conformance with its approved labeling and your servicing veterinarian's written prescription and did not comply with 21 C.F.R. Part 530, you caused the drug to be unsafe under section 512(a) of the FD&C Act, 21 U.S.C. § 360b(a), and adulterated within the meaning of section 501(a)(5) of the FD&C Act, 21 U.S.C. § 351(a)(5).

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute is in compliance with the law.

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include an update for each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Stephen J. Rabe, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about this letter, please contact Compliance Officer Rabe at 513-679-2700, ext. 2163 or stephen.rabe@fda.hhs.gov.

Sincerely,
/S/
Paul J. Teitell
District Director

Cincinnati District

R. L. Sommers, D.V.M.
Silver Lake Veterinary Clinic
9347 South State Road 15
Silver Lake, Indiana 46982

Ohio Department of Agriculture
Division of Animal Health
8995 East Main Street
Reynoldsburg, OH 43068-3399

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1. http://www.fda.gov/

# EXHIBIT 10

## Inspections, Compliance, Enforcement, and Criminal Investigations

## Ronald Andio, DBA Patron Farms, LLC 7/9/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2761

**WARNING LETTER**
**CIN-12-312058-26**

July 9, 2012

Via United Parcel Service

Mr. Ronald A. Andio, Owner
Ronald Andio, DBA Patron Farms, LLC
4445 South Turner Road
Canfield, Ohio 44406

Dear Mr. Andio:

On April 03, 05, and 30, 2012, the U.S. Food and Drug Administration (FDA) conducted an investigation of your livestock operation located at 4445 South Turner Road, Canfield, Ohio 44406. This letter notifies you of the violations of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) that we found during our investigation of your operation. You can find the FD&C Act and its associated regulations on the Internet through links on FDA's web page at www.fda.gov[1].

We found that you offered for sale an animal for slaughter as food that was adulterated. Under section 402(a)(2)(C)(ii) of the FD&C Act, 21 U.S.C. 342(a)(2)(C)(ii), a food is deemed to be adulterated if it bears or contains a new animal drug that is unsafe under section 512 of the FD&C Act, 21 U.S.C. 360b. Further, under section 402(a)(4) of the FD&C Act, 21 U.S.C. 342(a)(4), a food is deemed to be adulterated if it has been held under insanitary conditions whereby it may have been rendered injurious to health.

Specifically, our investigation revealed that on or about August 20, 2011, you sold a bay thoroughbred gelding horse, identified with back tag **(b)(4)** (USDA Tag **(b)(4)**) for slaughter as food. On or about August 23, 2011, **(b)(4)** slaughtered this animal. The Canadian Food Inspection Agency (CFIA) analysis of tissue samples collected from this animal identified the presence of phenylbutazone at 0.0025 parts per million (ppm) in the muscle tissue and 0.026 ppm in the kidney tissue and clenbuterol at 0.0039 ppm in the eye (target tissue). FDA has not established a tolerance for residues of phenylbutazone and clenbuterol in the edible tissues of horses. The presence of these drugs in edible tissues from this animal in these amounts causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii).

Our investigation also found that you hold animals under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you failed to inquire about the medication status of animals purchased for

slaughter. Food from animals held under such conditions is adulterated within the meaning of section 402(a)(4) of the FD&C Act, 21 U.S.C. 342(a)(4).

The violations listed above are not intended to an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. As a dealer of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, the adulterated animals. As such, you share responsibility for violating the Federal Food, Drug and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1. Implementing a system to determine from the source of the animals whether the animals has been medicated and with what drug(s); and

2. If the animal has been medicated, implementing a system to withhold the animal from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissue. If you do not want to hold the medicated animal then it should not be offered for human food, and it should be clearly identified and sold as a medicated animal.

You should take prompt action to correct the violations described in this letter and to establish procedures to ensure that these violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

We also note that the slaughterhouse has on file an Equine Information Document (EID) certificate (or guarantee) dated August 23, 2011 from the producer stating that this animal that you sold had not been administered any drugs or vaccines or treated with any substances not permitted for use in food processing equine in the last 180 days prior to your purchase of this animal. During our inspection of your firm, you admitted that you filled out and signed the producer's name to this form and did not inquire of the producer the medication status of this animal. You provided this EID to the dealer who purchased this animal from you. Providing such a false guaranty is prohibited by section 301(h) of the FD&C Act, 21 U.S.C. 331(h). You should take appropriate actions to ensure that this violation does not recur.

You should notify this office in writing of the steps you have taken to bring your firm into compliance with the law within fifteen (15) working days of receiving this letter. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days of receiving this letter, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your written response should be sent to Mr. Mark E. Parmon, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about this letter, please contact Compliance Officer Mark E. Parmon at (513) 679-2700, Ext. 2162, (513) 679-2773 (fax), or email: mark.parmon@fda.hhs.gov.

Sincerely yours,

/S/

Paul J. Teitell
District Director
Cincinnati District

cc: Dr. Tony Forshey, Acting Chief
Ohio Department of Agriculture
8995 East Main Street
Reynoldsburg, OH 43068-3399

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

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