United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

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Dear Mr. Wagman:

The Food Safety and Inspection Service (FSIS) has completed its review of the petition you submitted on behalf of Front Range Equine Rescue and the Humane Society of the United States dated April 6, 2012. The petition asserts that meat and meat food products from horses without a proven lifetime history of all drugs, treatments, and substances administered to the animal are adulterated under the Federal Meat Inspection Act (FMIA) and as such must be prohibited for human food. To prevent these products from entering the human food supply, the petition requests that FSIS initiate rulemaking to require that any horse offered for slaughter for human food be identified as "U.S. Condemned" unless the slaughter establishment receiving or buying the horse obtains: 1) an accurate record of all of the horse's prior owners; 2) a record of all drugs, treatments, and substances administered to the horse since birth; and 3) verification that the horse has at no time been exposed to any substances prohibited for use in animals intended for human food. The petition also requests that FSIS issue regulations to require that any horse or horsemeat that meets the criteria described above be tested for the presence of all potentially dangerous substances in a manner that ensures detection of any residue or any potentially dangerous substance. The petition states that if any potentially dangerous substance is found, or if testing is not available to determine the presence of any prohibited substances, the regulations must require that the horse or horsemeat be identified as "U.S. Condemned."

FSIS has also reviewed the supplemental statement that you submitted on February 19, 2013, which contains declarations from several veterinarians and horse owners attesting that horses are routinely treated with a variety of veterinary drugs.

After carefully considering the issues raised in the petition and the supplemental statement, the Agency finds no merit in the assertion that all meat and meat food products from a horse without a proven lifetime history of all substances administered to it are adulterated under the FMIA. FSIS has concluded that its existing authority under the FMIA and implementing regulations, which include requirements for the disposition of livestock suspected of having biological residues, along with the Agency's National Residue Program (NRP), will allow the Agency to ensure that carcasses and horsemeat products that bear the mark of inspection are safe for human food. FSIS is able to fully carry out the purposes and achieve the ends of the FMIA to make certain that meat and meat food products from horses do not contain violative residues or other substances that would adulterate these products. Thus, for the reasons discussed below, the Agency is denying the petition.

As noted in your petition, under the FMIA, a meat or meat food product is adulterated if, among other circumstances: 1) it contains any added poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1)); 2) it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or deleterious substance that would make such article unfit for human food (21 U.S.C. 601(m)(2)); 3) it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 601(m)(2)); or 4) it is "otherwise unfit for human food" (21 U.S.C. 601(m)(3)).

The petition and the supplemental statement assert that the variety of drugs administered to American horses makes their meat unfit for human food and thus adulterated under the FMIA because these drugs cannot legally be administered to food animals in any amount. To support this assertion, the petition includes an illustrative list of substances that bear the labeling statement: "Do not use in horses intended for human consumption" but that are routinely given to American horses. The petitioner claims that if a horse is treated with a substance that bears this labeling statement – at any point in its lifetime – any meat from the animal is unfit for human food and must be condemned. The petition also asserts that many substances administered to American horses are unsafe food additives, result in drug residues prohibited in meat in any amount, or render horsemeat "injurious to health."

FSIS disagrees with this interpretation and finds no basis in the statute or in science to support the petitioner's conclusion that meat from every horse treated with a substance listed in the petition is adulterated under the FMIA. The fact that a drug or other chemical was administered to an animal does not by itself mean that the meat and meat food products from the animal will be adulterated because administration of a substance does not necessarily affect the meat or meat food products derived from the animal. Residues do not remain in animals forever; they are eliminated from the body over time. After a substance has been administered to a horse, the drug would be excreted from the animal's system and would eventually leave no detectable residue. If no detectable drug or chemical residue remains in the animal at the time of slaughter, then the meat from that animal is not adulterated because there is no reason to believe that the meat will cause harm to human consumers, or that the meat is otherwise unfit for human food. Thus, the fact that a substance labeled "Do not use in horse intended for human food" was administered to a horse does not mean that the meat from the horse will be adulterated if the horse is eventually slaughtered for human food. The meat from that horse would be considered adulterated only if it contained residue of the substance.

Furthermore, FSIS fully protects consumers from harm by enforcing a zero tolerance (*i.e.*, no detectable levels permitted) policy for substances in horsemeat. FSIS enforces tolerance and action levels set by the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) to ensure that meat and meat food products do not contain levels of animal drugs, pesticides, or other chemicals above the level that is considered safe. If there is no established tolerance for a substance, FSIS condemns the entire carcass of an animal that tests positive for that substance and prohibits its use for human food.

Because there are no tolerance levels for substances administered to horses, if a residue test reveals any amount of the substance in a horse, FSIS will condemn all meat from that horse. In addition, FSIS will conduct intensified residue testing at establishments that slaughter horses. FSIS has no reason to believe that it cannot use its existing authority to effectively target and enforce its zero tolerance policy for substances in horsemeat.

The petition asserts that the NRP and FSIS's sampling programs – the Scheduled Sampling Program and the Inspector Generated Sampling Program – would not be able to prevent the entry of adulterated horsemeat into the food supply. To support this assertion, the petitioner cites the Office of Inspector General's 2010 Report on the NRP for cattle (Audit Report 24601-08-KC). The petition asserts that the only way to ensure the safety of horsemeat is to establish a system that captures the history of drug use on each animal, similar to that employed by the European Union (E.U.). We disagree.

Food safety problems may arise at many points along the farm-to-table continuum for all amenable species, not just for horses. FSIS finds no merit in the petitioner's argument that the Agency's use of the NRP and the residue sampling program would not be effective in preventing adulterated horsemeat from entering the human food supply. FSIS has addressed the recommendations made by the OIG in 2010 and has made several improvements to strengthen the NRP and its inspection and sampling programs in the past three years. For example, FSIS has implemented several multi-residue methods for analyzing samples of meat and meat food products for animal drug residues, pesticides, and environmental contaminants. FSIS has validated the multi-residue methods for horsemeat. These methods allow the Agency to screen for chemical compounds that include several types of legal and illegal drugs, such as antibiotics, anti-inflammatories, and growth hormones. The petitioner was especially concerned about the use of phenylbutazone in horses. FSIS's methods can detect phenylbutazone as well as nine classes of antimicrobials from sulfas to penicillin; anti-inflammatory drugs like flunixin; anti-parasitic drugs like avermectins; several heavy metal and environmental contaminants; over 50 types of pesticides; and performance altering drugs such as the beta-agonists, clenbuterol and ractopamine. In the past, FSIS would have had to collect samples from horses and look for just one chemical at a time. However, under FSIS's new system, one sample can be screened for over 130 different compounds.

FSIS's NRP includes sampling from show animals and other livestock that, similar to horses, are not specifically raised for human food. Like all livestock that are offered for slaughter, these animals do not arrive at slaughter with a full history of drug use. To ensure that meat from show animals does not contain residues that would adulterate the meat under the FMIA, FSIS inspectors collect residue samples from these animals at a higher rate than they do for other livestock. FSIS will collect residue samples from horses in a manner similar to its residue sampling for show animals. Inspection program personnel will tag horses that appear unhealthy, that have visible needle puncture marks, or exhibit signs or symptoms associated with the effects of a particular substance as "U.S. Suspect" and perform inspector-generated testing. In addition, as they do for show animals, FSIS inspection program personnel will randomly select and sample a number of carcasses from every lot of horses that pass ante-mortem inspection.

Thus, the rate at which we will collect samples for horses will be be higher than the rate at which we collect samples from other livestock. The Agency will evaluate the results of residue testing from horses to determine the need to adjust its sampling rate as it gains experience with horse slaughter.

As noted in the petition, the Hazard Analysis and Critical Control Points (HACCP) inspection system regulations (9 CFR 417.2(a)(3)) make clear that violative residues present a food safety hazard that may be reasonably likely to occur, and, therefore, slaughter establishments must consider the likelihood of their occurrence in developing HACCP plans. The HACCP regulations provide that a "…hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed" (9 CFR 417.2(a)). Because of concerns about residues in horses, FSIS expects that an establishment that slaughters horses will incorporate controls for residues in its HACCP system. These controls could include independent sampling and testing for residues or requesting suppliers to certify that the horses are residue-free. The Agency will verify that an establishment that slaughters horses has addressed violative residues in its hazard analysis and will verify that the establishment's HACCP system is effective in preventing horsemeat containing residues that would adulterated the meat under the FMIA from entering the human food supply. FSIS will take action against an establishment that does not have an adequate chemical residue control program in place (see FSIS Directives 5,000.1 and 10,800.1).
For example, if the Agency determines that an establishment's residue controls are ineffective, the Agency is authorized to take action and retain products because the products would have been produced under conditions that preclude the Agency from determining product is not adulterated (9 CFR 500.2(a)(2)).

In addition, FSIS maintains a list of animal producers that are repeat residue violators. The Residue Repeat Violators List includes producers associated with more than one violation on a rolling 12-month basis. The list will provide helpful information to horse processors and producers, serve to deter violators, and enable FSIS to make better use of its resources.

Furthermore, FSIS has recently issued a compliance guide to help livestock slaughter establishments avoid purchasing animals with illegal drug or other violative chemical residues. The compliance guide is available on FSIS's Web site at http://www.fsis.usda.gov/PDF/Residue_Prevention_Compliance_Guide_042512.pdf. The compliance guide focuses on establishments that slaughter cull dairy cows and bob veal because these animals account for 90 percent of the residues found in animals presented for slaughter; however, the compliance guide would be applicable to establishments that slaughter horses because applying the five basic measures suggested in the guidance would reduce or prevent the occurrence of residues that violate the FMIA.

The guide recommends that establishments: 1) confirm producer history; 2) buy animals from producers who have a history of providing residue-free animals and have effective residue prevention programs; 3) ensure that animals are adequately identified to enable traceback; 4) demonstrate that animals in a lot presented for ante-mortem inspection did not come from producers identified as repeat violators; and 5) notify producers in writing if their animals are found to have either residues that would adulterate the meat or residues at detectable levels that do not exceed established tolerance levels.

The petition also claims that allowing establishments to slaughter horses would pose a danger to the environment. To support this claim, the petitioner states that one slaughter facility in Texas was cited for wastewater violations and other nuisance violations. The petition asserts that the National Environmental Policy Act (NEPA) requires FSIS to prepare an environmental assessment (EA) or an environmental impact statement (EIS) before approving a grant of inspection to a horse slaughter facility.

Each USDA agency must comply with 7 CFR part 1b of the Departmental regulations, which supplements the NEPA regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an EA or an EIS unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)). FSIS will decide on a plant-by-plant basis whether the categorical exclusion properly applies to issuing a grant of inspection to a horse slaughter establishment, or whether it is necessary for FSIS to prepare an EA or EIS.

Finally, the petition asserts that it is not possible to slaughter horses in a humane manner. In support of this assertion, the petition cites four FSIS noncompliance records (NRs), issued from 2005-2007, that document inhumane handling of horses. According to the petition, ill, diseased, and injured horses are unfit for food under the FMIA and should not be slaughtered for human consumption.

FSIS finds no merit in the petition's conclusion that it is not possible to slaughter horses in a humane manner. In FSIS's experience, inhumane handling incidents are rare and do not accurately depict behavior throughout the industry. From 2005 to 2007, FSIS issued only 12 NRs for humane handling violations in horse slaughter establishments. The NRs demonstrate that FSIS will take appropriate action to detect and prevent inhumane handling incidents.
In addition, FSIS has made significant changes to its inspection program in the years since these NRs were issued. FSIS has put more emphasis on animal handling inspection and has provided clarification and training on humane handling verification and enforcement activities to inspectors (see FSIS's Livestock Slaughter Inspection Training available at http://www.fsis.usda.gov/PDF/LSIT_HumaneHandling.pdf ). Inspectors in establishments that slaughter horses will be required to complete such training.

As noted in the petition, the Humane Methods of Slaughter Act of 1978 (HMSA) requires livestock, including horses, to be humanely handled in connection with slaughter.

FSIS will take action against an establishment that does not comply with the HMSA and the regulations that implement it.
The petition also asserts that horses cannot be humanely transported to slaughter. USDA's Animal and Plant Health Inspection Service (APHIS) has authority over the commercial transportation of horses to slaughter and has enacted regulatory requirements for such transport (9 CFR Part 88). FSIS cooperates with APHIS in enforcing APHIS's humane transport requirements and will continue to cooperate with APHIS to enforce APHIS's requirements for the commercial transportation of horses. For example, FSIS inspectors will monitor the off-loading of horses at slaughter establishments, and if a horse arriving at a slaughter facility on a transport vehicle is not capable of standing on all four legs, FSIS inspectors will contact the APHIS Area Veterinarian-in-Charge. APHIS will send follow-up veterinary personnel to the facility to conduct an investigation.

For these reasons, FSIS is denying the petition requesting that the Agency amend its regulations governing the processing of horses and horsemeat intended for human consumption. FSIS has concluded that its existing regulations and the NRP would be effective in ensuring that adulterated horsemeat does not enter the human food supply.

In accordance with FSIS regulations, the petition was posted on the FSIS website in April 2012, and the Agency intends to post this response as well.

Sincerely,

Charles E. Williams
for

Rachel A. Edelstein
Assistant Administrator
Office of Policy and Program Development