IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

No. 13-2187

FRONT RANGE EQUINE RESCUE, *et al.*,
Plaintiffs-Appellants

and

THE STATE OF NEW MEXICO,
Plaintiff-Intervenor-Appellant

v.

TOM VILSACK, Secretary of the
U.S. Department of Agriculture, *et al.*,
Defendants-Appellees

and

RESPONSIBLE TRANSPORTATION, LLC, *et al.*,
Defendants-Intervenors-Appellees

On Appeal from the United States District Court for the
District of New Mexico (Hon. M. Christina Armijo)

FEDERAL APPELLEES' RESPONSE TO APPELLANTS' EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL

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Plaintiffs Front Range Equine Rescue, *et al.* and Plaintiff-Intervenor the State of New Mexico (collectively, "Front Range") seek the extraordinary remedy of an injunction pending appeal to halt Defendant-Appellee U.S. Department of Agriculture's (USDA) provision of inspection services to horse slaughter facilities meeting the requirements of the Federal Meat Inspection Act, 21 U.S.C. §§ 601–625. Front Range argues that, prior to carrying out its nondiscretionary duty of granting inspections to facilities meeting all legal requirements, the USDA Food Safety and Inspection Service (FSIS) was required to prepare an environmental assessment (EA) or even a full-blown environmental impact statement (EIS) pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321 *et seq.* Front Range also challenges FSIS's internal instructions to its agency employees on how to carry out these inspections.

This Court should deny Front Range's motion for an injunction pending appeal. Front Range does not demonstrate a likelihood of success on its claims that NEPA applies to FSIS's nondiscretionary duty and that a revocable, non-binding internal agency directive triggers NEPA requirements.[1] Moreover, the equities weigh against granting the injunction. Front Range fails to establish any non-speculative, imminent, irreparable injury to its concrete interests. Its allegations of irreparable injury are based on conjecture and speculative fears of "contamination" of local

[1] Indeed, Front Range does not even attempt to show that the district court erred in holding that NEPA does not apply to the Directive, and thus has waived that claim as the basis for their motion.

waters. FSIS's regulations and directives for the inspection, testing, handling, and labeling of livestock, including equines, include a drug residue testing program for all livestock. Any detection of a drug residue will result in the carcass being condemned. The unfounded fears of Front Range's declarants do not support a finding of irreparable injury, and Front Range's motion should be denied.

A. STATUTORY AND REGULATORY BACKGROUND

1. Federal Meat Inspection Act — Congress enacted the Federal Meat Inspection Act ("the Act") in 1907, "after Upton Sinclair's muckraking novel *The Jungle* sparked an uproar over conditions in the meatpacking industry." *Nat'l Meat Ass'n v. Harris*, 132 S.Ct. 965, 968 (2012). The Act, as amended, "regulates a broad range of activities at slaughterhouses to ensure both the safety of meat and the humane handling of animals." *Id.* The statute applies to certain "amenable species," including "cattle, sheep, swine, goats, horses, mules, and other equines." 21 U.S.C. § 601(w).

The Act imposes a nondiscretionary duty on FSIS to grant inspections at slaughter facilities meeting the requirements of the Act. FSIS "shall" inspect all "amenable species" prior to their "be[ing] allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce." 21 U.S.C. § 603(a). The Act also requires that FSIS "shall" inspect "the carcasses and parts thereof of all amenable species to be prepared at any slaughtering,

meat-canning, salting, packing, rendering, or similar establishment in [the United States] as articles of commerce which are capable of use as human food." *Id.* § 604. The Act prohibits the sale or transport "in commerce" of any article involving amenable species "or any carcasses, parts of carcasses, meat or meat food products of any such animals" if the article has not been "inspected and passed" by FSIS in accordance with the Act. *Id.* § 610(c).

Inspections under the Act must be conducted by "inspectors appointed for that purpose." 21 U.S.C. §§603(a), 604. FSIS, as the delegate of the Secretary of Agriculture, is responsible for "caus[ing]" those inspections to take place. *Id.* §§601(a), 603(a), 604; 7 C.F.R. §2.53(a)(2)(ii). "[E]ach person conducting operations at an establishment subject to [the Act]" must "make application" to FSIS before "inspection is granted." 9 C.F.R. §304.1(a). "[FSIS] is authorized to grant inspection upon [its] determination that the applicant and the establishment are eligible therefor and to refuse to grant inspection at any establishment if [FSIS] determines that it does not meet the requirements." *Id.* at §304.2(b).

2. NEPA — NEPA is a procedural statute that requires federal agencies proposing "major Federal actions significantly affecting the quality of the human environment" to prepare an EIS. 42 U.S.C. § 4332(2)(C). Implementing regulations, 40 C.F.R. §§ 1500–08, allow an agency to comply with NEPA in one of three ways. First, an agency may prepare an EIS, 40 C.F.R. § 1501.3. Second, it may prepare an EA, *see id.* §§ 1501.4(b), 1508.9, to determine whether the action will have a

"significant" effect on the environment and therefore require preparation of an EIS. Third, if the agency determines that the proposed action falls within an established "categorical exclusion" or "CE," it does not need to prepare an EA or an EIS. *See id.* §§ 1501.4(a)(2), 1501.4(b); *West v. Sec'y of Dep't of Transp.*, 206 F.3d 920, 926–27 (9th Cir. 2000). CEs are defined as "categor[ies] of actions which do not individually or cumulatively have a significant effect on the human environment and which have been found to have no such effect in [NEPA] procedures adopted by a Federal agency." 40 C.F.R. § 1508.4. USDA has categorically excluded FSIS's programs and activities from NEPA requirements. 7 C.F.R. § 1b.4(6).

B. FACTUAL BACKGROUND

Three facilities are at issue in this appeal. Valley Meat Company, LLC ("Valley Meat") is a small cattle slaughter and processing facility in Roswell, New Mexico. *See* Valley Meat Decision Memo at ECF p.4, Pl. Exh. 10 ("Valley DM"). Its current owner has conducted federally-inspected commercial slaughter of cattle and other species at the facility since approximately 1991. *Id.* On March 2, 2012, Valley Meat applied to FSIS to receive inspection services for the commercial slaughter of horses, mules, and other equines for human consumption. Valley DM at 4. On June 27, 2013, FSIS approved Valley Meat's application, after concluding that the action fell within the CE and that no extraordinary circumstances existed that would cause the action to have a significant environmental effect and trigger NEPA requirements. *Id.* at 8.

Responsible Transportation, LLC, is a facility located in Sigourney, Iowa. *See* Responsible Transportation Decision Memo at ECF p.3, Pl. Exh. 16 ("RT DM"). The facility was previously used for processing beef products. *Id.* On December 13, 2012, Responsible Transportation filed an application with FSIS to grant federal meat inspection services for commercial horse slaughter operations for human consumption. *Id.* FSIS approved Responsible Transportation's application after finding it to be consistent with the CE. *Id.*

Rains Natural Meats in Gallatin, Missouri, submitted an application on January 15, 2013, and FSIS is in a position to issue a grant of inspection pending resolution of this action. *See* Fed. Exh. 1, Engeljohn Decl. ¶ 7; *see also* Dist. Dkt. 154. FSIS issued a corrected CE decision for the Rains facility on October 21, 2013, *see* Dist Dkt. 201, but was enjoined by the district court from granting inspections. Dist. Dkt. 142, 179.

On June 28, 2013, FSIS issued Directive 6130.1. Pl. Exh. 13. This internal agency guidance provides instructions to FSIS inspectors "on how to perform ante-mortem inspection of equines before slaughter and post mortem inspection of equine carcasses and parts after slaughter." *Id.* at 1. The Directive also instructs FSIS inspectors on "making ante-mortem and post-mortem dispositions of equines, how to perform residue testing, verify humane handling, verify marking of inspected equine products, and document results." *Id.* The Directive requires FSIS inspectors to conduct intensified random drug residue testing of healthy-appearing equines. *Id.* at 6–7. While inspectors will test equines more frequently than many other types of

livestock slaughtered for human consumption, the method for testing equine tissue is not different from the method for testing other types of livestock. *See* Engeljohn Decl. ¶¶ 8–10, 14–16. The drug residues tested include those of potential public health concern for all livestock, including equines. *Id.*

C. PROCEDURAL HISTORY

On August 2, 2013, the district court granted Front Range's request for a temporary restraining order enjoining USDA "from dispatching inspectors to the . . . facilities operated by Intervenor[s]-Defendants Valley Meat and Responsible Transportation until further order of the Court." Pl. Exh. 18, Order at 6–7. On September 20, 2013, in response to USDA's notice that it was prepared to issue a grant of inspection for Intervenor-Defendant Rains Natural Meats, *see* Pl. Exh. 15, the district court issued an order enjoining USDA from dispatching inspectors to Rains' facility. Dist. Dkt. 168. On September 25, 2013, the parties stipulated to extend the effectiveness of the temporary restraining order until October 31, 2013, the date by which the district court expected to issue its decision on the merits. Dist. Dkt. 178. On November 1, 2013, the district court affirmed USDA's actions granting inspections and denied Front Range's request for a permanent injunction. Dist. Dkt. 205. This appeal followed, and on November 2, 2013, Front Range filed a motion for an injunction pending appeal in this Court, without first doing so in the distort court. On November 4, this Court entered a temporary injunction to give it additional time to consider the motion.

STANDARD FOR AN INJUNCTION PENDING APPEAL

Preliminary injunctions are "extraordinary" remedies. *SCFC ILC, Inc. v. Visa USA, Inc.*, 936 F.2d 1096, 1098 (10th Cir. 1991). To obtain this extraordinary relief, Front Range bears the burden of establishing, by "clear and unequivocal" evidence: (1) a likelihood of success on the merits, (2) the threat of irreparable harm to Front Range if the injunction is not granted, (3) that the balance of equities tips in Front Range's favor, and (4) that an injunction is in the public interest. *Atty. Gen. of Ok. v. Tyson Foods, Inc.*, 565 F.3d 769, 776 (10th Cir. 2009); *see* 10th Cir. R. 8.1.

Front Range incorrectly asserts that if it establishes "that the three harm factors tip decidedly in its favor, the probability of success requirement is somewhat relaxed." Mot. 9. This standard did not survive *Winter v. NRDC*, in which the Supreme Court held that plaintiffs must demonstrate that they are both "likely to succeed on the merits" and "likely to suffer irreparable harm in the absence of preliminary relief." 555 U.S. 7, 20 (2008). This leaves no room for this Court to relax the merits factor of the injunction test, even if Front Range were to make a strong showing on the irreparable harm factor — which it has not done.

ARGUMENT

I. FRONT RANGE HAS NOT DEMONSTRATED A LIKELIHOOD OF SUCCESS ON THE MERITS OF ITS CLAIMS

A. NEPA Does Not Apply to FSIS' Grants of Inspection

Front Range is unlikely to prevail on the merits of its NEPA claims. "The

touchstone of whether NEPA applies is discretion. . . . [If] the agency does not have sufficient discretion to affect the outcome of its actions, and its role is merely ministerial, the information that NEPA provides can have no [e]ffect on the agency's actions." *Citizens Against Rails-To-Trails v. Surface Transp. Bd.*, 267 F.3d 1144, 1151 (D.C. Cir. 2001); *see also Public Citizen v. Dep't of Transp.*, 541 U.S. 752, 756, 759 (2004); *Sac & Fox Nation of Mo. v. Norton*, 240 F.3d 1250, 1262 (10th Cir. 2001).

The Act *requires* FSIS to grant inspections of facilities that meet applicable humane handling and food safety requirements. If those conditions are met, FSIS does not have discretion to deny or condition a grant of inspection on environmental grounds. Therefore, as the district court correctly found, NEPA's environmental review provisions do not apply here. *See* 40 C.F.R. § 1502.14.

Congress plainly provided in the Act that "[f]or the purpose of preventing the use in commerce of meat and meat food products which are adulterated," FSIS "*shall* cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, . . . or similar establishment" and that "when so slaughtered the carcasses of said amenable species *shall* be subject to a careful examination and inspection." 21 U.S.C. § 603(a) (emphasis added). Likewise, "[f]or the purpose of preventing the inhumane slaughtering of livestock," FSIS "*shall* cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method

by which amenable species are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter." *Id.*§ 603(b) (emphasis added). The Act further requires FSIS to make post-mortem inspections and to mark "carcasses and parts thereof" of animals not adulterated as "Inspected and passed" and those that are adulterated to be marked "Inspected and condemned." 21 U.S.C. § 604.

As the district court correctly found, any doubt that the Act plainly limits FSIS's discretion is resolved by the legislative history of the statute. The House and Senate Reports for the 1967 Amendments to the Act both indicate that 21 U.S.C. § 603(a) was amended to replace "the Secretary of Agriculture, at his discretion, *may*" provide inspectors for ante-mortem inspections with "the Secretary *shall*" provide such inspectors. *See* Fed. Exh. 2 at 33; Fed. Exh. 3 at 26. The House Report states that this amendment would "[m]ake ante mortem inspection mandatory rather than permissive." Fed. Exh. 2 at 6; *see also id.* at 26 (same). Front Range's argument that FSIS enjoys discretion in granting inspections is contrary to both the plain language of the Act and its legislative history.

In accordance with the Act, USDA and FSIS have promulgated detailed regulations governing the slaughter of all amenable species, including equines, that are subject to the Act's mandatory inspection requirements. *See* 9 C.F.R. § 300.1 through § 500.7. These regulations focus on ensuring that animals are slaughtered humanely and that the meat products are unadulterated. *See*, *e.g.*, 9 C.F.R. §305.3

("Inspection shall not be inaugurated if an establishment is not in sanitary condition"). Under the regulations, FSIS may take only one of two actions on an application for a grant of inspection: 1) grant the application if the facility meets the requirements of the Act and its implementing regulations, or 2) deny the application if the facility does not meet the requirements. *See* 9 C.F.R. § 304.2(b).

In its decision granting inspection at the Valley Meat facility, FSIS explained that its action is "purely ministerial," and not discretionary:

> [I]f a commercial horse slaughter plant meets all of the statutory and regulatory requirements for receiving a grant of federal inspection services, FSIS has no discretion or authority under the [Act] to deny the grant on other grounds or to consider and choose among alternative ways to achieve the agency's statutory objectives. Therefore, a grant of federal inspection services under the [Act] is not . . . subject to NEPA requirements.

Pl. Exh. 10, Valley DM at 6. As a result of this limited authority, "FSIS inspectors will not have any authority or control over the day-to-day operations of the [Valley Meat] slaughter plant save to the degree necessary to achieve the agency's mission to protect public health by ensuring that horse meat intended for use as human food is safe to eat and properly labeled." *Id.* FSIS's explanation of its circumscribed authority is grounded in the clear language of the Act.

Front Range suggests that because FSIS "is authorized to grant inspection," Mot. 14, the agency's grants of inspection applications are discretionary and subject to NEPA review. This argument reads the words "is authorized" in isolation while

ignoring what the regulations authorize. Section 304.2(b) provides that the Administrator of FSIS:

> is authorized to grant inspection *upon his determination that the applicant and the establishment are eligible* therefor and to refuse to grant inspection at any establishment *if he determines* that it does not meet the requirements of this part or the regulations in . . . this chapter.

Id. (emphasis added).

Thus, neither the Act nor its implementing regulations authorizes FSIS to deny an application or condition the granting of the application on environmental considerations. As the Supreme Court held in *Public Citizen*, "where an agency has no ability to prevent a certain effect due to its limited statutory authority over the relevant actions, the agency cannot be considered a legally relevant 'cause' of the effect," and need not consider such effects "when determining whether to prepare a full EIS due to the environmental impact of an action it could not refuse to perform." 541 U.S. at 770.

That FSIS may exercise some judgment in determining whether an applicant meets statutory criteria does not grant the agency discretion "to add another entirely separate prerequisite to that list." *See Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 671–72 (2007). FSIS's authority is narrowly circumscribed by the Act, and it is well settled that NEPA does not enlarge that discretion. *See, e.g., S. Coast Air Quality Mgmt. Dist. v. FERC*, 621 F.3d 1085, 1092 (9th Cir. 2010).

In sum, Front Range fails to demonstrate in its motion that it is likely to succeed on the merits of this claim.

B. Even if NEPA Applied, FSIS Properly Found That Its Actions Were Categorically Excluded From Further NEPA Review

Because NEPA does not apply to FSIS's actions here, that is the end of the inquiry and Front Range cannot succeed on the merits. Nonetheless, even if NEPA did apply to FSIS's grants of inspection for Valley Meat, Rains, and Responsible Transportation, Front Range still would have no likelihood of success on its NEPA claims. Front Range argues that "NEPA review is required anytime a mere possibility of significant such effects exists," and asserts — based on layperson declarations regarding past operations at other plants that have no known ties to the facilities that are the subject of this litigation — that significant environmental effects are likely here. *See* Mot. 9–10. These assertions are flawed.

FSIS satisfied any NEPA obligations by invoking the CE in USDA's regulations. The regulations expressly identify FSIS as one of several agency units that "conduct programs and activities that have been found to have no individual or cumulative effect on the human environment," and consequently "are categorically excluded from the preparation of an EA or EIS unless the agency head determines that an action may have a significant environmental effect." 7 CFR § 1b.4(a), (b)(6).

Before invoking the CE, FSIS conducted a thorough assessment to ensure that the CE applied. *See* Pl. Exh. 10, Valley DM at 5–8; Pl. Exh. 16, RT DM at 4–7.

"Once an agency establishes categorical exclusions, its decision to classify a proposed action as falling within a particular categorical exclusion will be set aside only if a court determines that the decision was arbitrary and capricious." *Citizens' Comm.* 297 F.3d at 1023 (citations omitted).

1. The Grants of Inspection Do Not Pose Unique or Unknown Risks

The central premise of Front Range's NEPA argument is that there are "uncertain and unknown" effects from the presence of drug residues in horse flesh. Mot. 11–12.[2] This argument is based on Front Range's misunderstanding of USDA's residue testing program and is at odds with the record.

In the CE assessments for Valley Meat, Rains, and Responsible Transportation, FSIS examined the potential impacts of these facilities on environmental and other resources to ensure that there were no unique or extraordinary circumstances that would render the CE inapplicable. *See* Pl. Exh. 10, Valley DM at 8–13; Pl. Exh. 16, RT DM at 6–10. For instance, FSIS's CE assessment for Valley Meat specifically assessed Front Range's central claim that slaughter operations will cause significant public health risks and environmental impacts because horses are treated with pharmaceuticals and other chemicals that are not intended for use in animals destined for human consumption. *See* Mot. 4–5, 10–11. As an initial matter, FSIS —the expert

[2] Front Range also alleges "significant public controversy" over FSIS's actions. Mot. 11. But Front Range's general opposition to horse slaughter does not, in and of itself, make the inspection grants highly controversial such that preparation of an EIS is required. *See Anderson v. Evans*, 314 F.3d 1006, 1018–19 (9th Cir. 2002). *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1335 (9th Cir. 1992).

agency in this field — explained that merely because substances marked as not for use in horses intended for human consumption may have been administered to a horse during its lifetime does not mean that those substances remain in the animal at the time of slaughter, since residues "are eliminated from the [animal's system] over time, . . . eventually leaving no detectable residue." Fed. Exh. 4, AR1854.

Furthermore, to address concerns about drug residue in meat from all amenable species, FSIS developed the National Residue Testing Program. Front Range makes the conclusory assertion that FSIS has not presented "any scientific evidence" that the residue sampling "represents the most common substances present in horses." Mot. 11. This is a baseless claim, as FSIS's testing program was developed in coordination with experts from the Food and Drug Administration, Environmental Protection Agency, Agricultural Research Service, and Centers for Disease Control and Prevention. Engeljohn Decl. ¶12; AR199–200. The sampling system is based on prior findings of chemical compounds, veterinary drug inventories, information from investigations, and pesticides. *Id.*; *see also* AR2262 (history of residue testing in horses); AR1825–52 (Decision Memo on Development of Equine Slaughter Inspection Regime).

As explained in the CE assessments, FSIS will screen meat produced at the facility to ensure that it does not contain any such drug residues before it enters the chain of commerce. *See, e.e.*, Pl. Exh. 10, Valley DM at 8. Consumers are protected from harm by FSIS's "zero tolerance" policy. Under that policy, no detectable levels

of substances for which FDA or EPA have not established tolerance levels are permitted. If meat contains such residues, it will be marked "condemned" and sent to a rendering facility, "thereby ensuring that it endangers neither public health and safety nor the local environment." *Id.*

Based on the drug residue screening process and the complex array of federal, State, and local laws regulating Valley Meat's operations, FSIS concluded that "commercial horse slaughter at Valley Meat has no more potential to have a significant impact on public health and safety than did the commercial slaughter of cattle, pigs, sheep, and goats that preceded it." *Id.* AR2476; *see also* AR3289 (reaching the same conclusion for Responsible Transportation); AR0004878 (Rains). This conclusion was not an abuse of discretion. From an environmental impact standpoint, there is nothing unique or extraordinary about the proposed operations at these three facilities. *See, e.g.*, AR3289 (Responsible Transportation); AR4878 (Rains). Indeed, in the event that evidence emerges suggesting a higher incidence of drug residue in equine carcasses than was previously observed prior to the congressional ban on equine slaughter inspection, FSIS has well-defined procedures for progressively and rapidly increasing the frequency of sampling healthy-appearing equines, even up to 100 percent. AR1855–56; Engeljohn Decl. ¶¶ 10, 16.

Front Range's assertions that the CE is inapplicable due to the possibility of environmental contamination are also unsupported. Mot. 5, 10. As the record shows, blood and other inedible byproducts will not be placed in local water systems or

contaminate groundwater. AR2476; AR2509; AR3288–89; AR4877. For example, at the Valley Meat facility, the inedible portions of all animals slaughtered are required to be denatured to prevent possible human use and placed in specially-marked containers identified as inedible product, and sent to an off-site rendering facility for appropriate destruction. Engeljohn Decl. ¶ 24; AR2510; AR2594–95.

2. The Grants of Inspection Do Not Establish a Precedent for Future Actions with Significant Effects

There is likewise no support for Front Range's argument that FSIS's actions are significant and trigger NEPA obligations because they "establish a template for horse slaughter plants." Mot. 12. In evaluating whether an action is "significant" because of precedential impact under 40 C.F.R. § 1508.27(b)(6), agencies look at "[t]he degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration." *Id.* Aside from the three defendant-intervenor facilities, other plants have not actively pursued completion of the grant process after their first submissions to FSIS, which were made more than one year ago. Engeljohn Decl. ¶ 7. At this time, FSIS has no reason to believe that any other facility can feasibly complete a successful grant application for equine slaughter and be ready to slaughter in the near future. *Id.* Nor is there any basis for a conclusion that the three grants at issue here represent a decision in principle about how future applications, if and when they are received, will be treated.

Front Range does not identify any decision in which FSIS adopted a "national program of horse slaughter." FSIS is doing nothing more than implementing its nondiscretionary statutory obligations under the Act for all amenable species, by granting inspections for qualifying facilities on a case-by-case basis.

3. Front Range Does Not Show That the Grants of Inspection Threaten Violation of Federal or State Law

Front Range also claims that a NEPA analysis was required because FSIS's actions threaten violations of other environmental laws or requirements. Mot. 12; *see* 40 C.F.R. § 1508.27(b)(10). But the only evidence in the record regarding these allegations is contained in Front Range's petition, which was accompanied by declarations from laypeople who claimed that operations at three now-closed facilities owned by other entities resulted in environmental harms. The record contains no declarations from experts or other evidence of a comparable nature that support Front Range's allegations that the three facilities at issue in this case will commit violations of environmental laws and regulations. In short, Front Range has not presented any record evidence that calls into question the agencies' expert determinations.

FSIS's well-supported invocation of USDA's CE for its grants of inspection at the Valley Meat, Responsible Transportation, and Rains facilities does not constitute an abuse of discretion. FSIS relied on the technical opinions of its qualified experts to determine that no unique and extraordinary circumstances exist that would indicate

the potential for significant environmental impacts, as discussed above. "[A]n agency must have discretion to rely on the reasonable opinions of its own qualified experts even if, as an original matter, a court might find contrary views more persuasive." *Marsh*, 490 U.S. at 378. Because FSIS properly invoked its CE, it was not required to prepare an EA or EIS. Thus, even if NEPA applies to these grants of inspection, Front Range's NEPA claims fail.

II. FRONT RANGE HAS NOT DEMONSTRATED THAT IT WILL SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION

Front Range's discussion of irreparable harm relies almost exclusively on an erroneous interpretation of case law regarding the nature of environmental injury. *See* Mot. 15–16 (citing cases). Contrary to Front Range's assertion, the Supreme Court has rejected a presumption of irreparable injury in environmental cases. *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 545–46 (1987). The gravity of the environmental harm is instead incorporated into the hardship balancing test, and thus no presumption of harm is necessary. *Id.* at 545.

To be irreparable, "an injury must be certain, great, actual and not theoretical." *Heideman v. S. Salt Lake City*, 348 F.3d 1182, 1189 (10th Cir. 2003) (citation and internal quotation marks omitted). Front Range must make a "specific showing that the environmental harm results in irreparable injury to their specific environmental interests." *Davis v. Mineta*, 302 F.3d 1104, 1115 (10th Cir. 2002).

Front Range fails to establish any non-speculative, imminent, irreparable injury to its concrete interests. Its allegations of irreparable injury are based on unsubstantiated fears of "contamination" of local waters or of fish living in those waters. *See, e.g.*, Pl. Exh. 20, Trahan Decl. ¶ 8 ("fear" of eating fish from local waters); *id.* ¶ 9 ("worried" about discharges into local waters); Gross Decl. ¶ 13 (same); Seper Decl. ¶ 6 (same). Front Range paints a gory picture of "horse blood in their faucets" and a "meat supply [that] has been contaminated by adulterated horse flesh," Mot. 18–19, but fails to present any scientific evidence of contamination in local waters or in other meat products or any reasonable expectation that such contamination will occur. In contrast, as discussed above, FSIS has set forth detailed regulations and directives for the inspection, testing, handling and labeling of livestock, including equines.

At bottom, Front Range's argument is that slaughtered horses *might* be contaminated, that this contamination *might* reach nearby waters, and that this contamination *might* enter those unidentified lakes and streams at which Front Range's members *might* be recreating. These attenuated, speculative allegations of harm are insufficient to establish irreparable injury. *See Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1151 (2013). Front Range fails to carry its burden of providing "clear and unequivocal" evidence of irreparable harm, and its motion can be rejected for this reason alone. *RoDa Drilling Co. v. Siegal*, 552 F.3d 1203, 1210 (10th Cir. 2009).

III. THE PUBLIC INTEREST WOULD NOT BE SERVED BY AN INJUNCTION PENDING APPEAL

A federal court must deny a preliminary injunction, even where irreparable injury to the movant exists, if the injunction is contrary to the public interest. *See Winter*, 555 U.S. at 22; *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312–13 (1982). Here, an injunction pending appeal is not in the public interest. Through the Act, Congress has mandated that FSIS "shall" conduct inspection of the slaughter and processing of livestock, including horses, to ensure its safety for human consumption. After years of effectively banning domestic slaughter of horses for human consumption through a funding provision foreclosing FSIS inspection of horse slaughter facilities, Congress reversed course and lifted the ban in 2011. Thus, Congress has chosen once again to require FSIS to grant inspections to facilities that meet the requirements of the Act and implementing regulation. When Congress has itself "decided the order of priorities in a given area," a court of equity must follow the "balance that Congress has struck" and lacks discretion to strike a different balance. *United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001); s*ee also Virginian Ry. v. System Fed'n No. 40*, 300 U.S. 515, 551–52 (1937).[3]

* * *

For the foregoing reasons, Front Range's motion should be denied.

[3] In light of the fact that Front Range fails to demonstrate a likelihood of success on the merits and fails to show that it will suffer irreparable harm in the absence of an injunction pending appeal, this pleading does not address the balance of harms.

Respectfully submitted,

/s Vivian H.W. Wang

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CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that the copy of the foregoing response submitted in digital form via the Court's ECF system is an exact copy of the written document filed with the Clerk. I further certify that all required privacy redactions have been made and that this brief has been scanned for viruses with Microsoft Forefront Client Security version 1.161.1618.0, virus definition file dated November 6, 2013, and, according to the program, is free of viruses.

November 7, 2013 /s/ Vivian H.W. Wang

CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2013, I electronically filed the foregoing using the Court's CM/ECF system which will send notification of such filing to all parties in this case.

/s/ Vivian H.W. Wang

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

No. 13-2187

FRONT RANGE EQUINE RESCUE, *et al.*,
Plaintiffs-Appellants

and

THE STATE OF NEW MEXICO,
Plaintiff-Intervenor-Appellant

v.

TOM VILSACK, Secretary of the
U.S. Department of Agriculture, *et al.*,
Defendants-Appellees

and

RESPONSIBLE TRANSPORTATION, LLC, *et al.*,
Defendants-Intervenors-Appellees

On Appeal from the United States District Court for the
District of New Mexico (Hon. M. Christina Armijo)

EXHIBITS TO FEDERAL APPELLEES' RESPONSE TO APPELLANTS' MOTION FOR INJUNCTION PENDING APPEAL

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Exhibit 1

Declaration of Dr. Daniel L. Engeljohn

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

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

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

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

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

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

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

[2] This State certification is the certification required by section 401 of the Clean Water Act (33 U.S.C. § 1341(a)).
[3] Unified Equine LLC submitted its application on April 25, 2012; Oklahoma Meat Company submitted its application on May 18, 2012; and Trail South LLC submitted its application on June 1, 2012.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Executed on July 19, 2013.

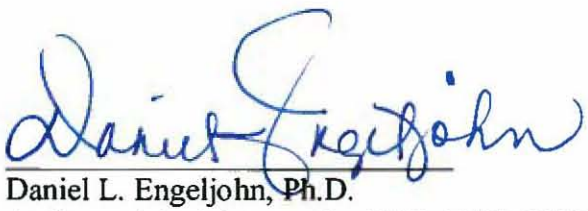

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Exhibit 2

House Report

90TH CONGRESS } HOUSE OF REPRESENTATIVES { REPORT
1st Session } { No. 653

FEDERAL MEAT INSPECTION ACT

SEPTEMBER 21, 1967.—Committted to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. POAGE, from the Committee on Agriculture, submitted the following

REPORT

together with

SUPPLEMENTAL VIEWS AND ADDITIONAL SUPPLEMENTAL VIEWS

[To accompany H.R. 12144]

The Committee on Agriculture, to whom was referred the bill (H.R. 12144) to clarify and otherwise amend the Meat Inspection Act, to provide for cooperation with appropriate State agencies with respect to State meat inspection programs, and for other purposes, having considered the same, report favorably thereon with amendments and recommed that the bill do pass.

The amendments are as follows:

Page 3, line 13, strike the word "territory" and insert in lieu thereof the word "Territory".

Page 3, line 18, strike the word "territory" and insert in lieu thereof the word "Territory".

Page 3, line 19, strike the word "territory" and insert in lieu thereof the word "Territory".

Page 3, line 22, strike the word "territories" and insert in lieu thereof the word "Territories".

Page 10, line 19, strike the word "or" and insert in lieu thereof the word "of".

Page 20, line 13, strike the period and insert the following:

: *Provided further*, That nothing in this section shall apply to any individual who purchases meat or meat products outside the United States for his own consumption except that the total amount of such meat or meat products shall not exceed fifty pounds.

TITLE I

Title I of the "Federal Meat Inspection Act" would both revise and incorporate various provisions of law now found in the act of March 4, 1907, the Horse Meat Act and the Imported Meat Act.

Specifically, title I would—

(1) Define various terms and then coordinate these definitions with the Food, Drug, and Cosmetic Act where appropriate.

(2) Provide a legislative finding that all articles regulated under the act are either in interstate or foreign commerce or are substantially affected by such commerce.

(3) Make ante mortem inspection mandatory rather than permissive.

(4) Make products "capable of use as human food" (rather than present act's language "prepared for human consumption") subject to inspection.

(5) Clarify the authority to limit the entry of meat into federally inspected plants.

(6) Clarify the Secretary's authority to regulate the marking, labeling, and packaging of meat and meat products shipped from federally inspected plants or distributed in commerce and to prescribe standards for containers.

(7) Prohibit the slaughter of animals and the preparation of products except when done in compliance with the act.

(8) Strengthen the prohibition against unauthorized use of an official inspection mark or similar item.

(9) Require foreign slaughtering and processing facilities to meet the same standards required to be met by U.S. firms operating in interstate commerce.

(10) Repeal the present farmer and retailer exemptions and replace them with more restrictive exemption provisions.

(11) Include all equine carcasses, meat and parts thereof, and meat products within the coverage of the act.

(12) Permit the Secretary to issue appropriate regulations.

TITLE II

Title II deals with the Secretary's authority over unwholesome meat products and would—

(1) Prohibit Federal inspection under title I of the act of articles not intended as human food.

(2) Require denaturing of such articles prior to distribution in commerce.

(3) Require recordkeeping and provide for the Secretary's access to such records by certain persons engaged in processing, handling, or transporting of various human and animal foods and "4–D" animals (i.e., dead, dying, disabled, or diseased).

(4) Permit registration of certain persons handling, processing, or transporting 4–D animals.

(5) Prohibit 4–D sales except as provided by the Secretary's regulations.

(6) Permit the Secretary to take necessary action when and if the States have not adequately met their responsibility to protect the public's meat supply.

SECTION 3

This section would make a nonsubstantive drafting change by deleting "interstate or foreign" before "commerce" in sections 3 through 23 of title I of the Federal Meat Inspection Act, in view of the definition of "commerce" in section 1 of this bill. It also would make ante mortem inspection mandatory and change the reference to "Secretary of Agriculture" throughout title I of the act to "Secretary," in view of the definition of "Secretary" in section 1 of this bill.

SECTION 4

This section would delete limiting language to make it clear that the post mortem inspection provisions of the act apply more broadly to articles "capable of use as human food" rather than merely to those intended for such use.

SECTION 5

This section would clarify the authority of the Secretary of Agriculture to restrict entry of carcasses, parts thereof, meat, and meat food products into establishments that are federally inspected under title I, to federally inspected articles moved directly from other federally inspected establishments or from other locations under conditions necessary to assure that the articles were federally inspected and are otherwise in compliance with the act. Authority to regulate the entry of other materials would also be clarified.

SECTION 6

The section would clarify the authority of the Secretary of Agriculture to regulate the marking, labeling, and packaging of articles specified in the bill, to prevent the use of false, deceptive or misleading marks, labels, or containers. This section also provides for judicial review of disapproval of marks, labels, and containers comparable to that contained in the Poultry Products Inspection Act (21 U.S.C. 457) which is similar to many of the provisions in this section of the bill. The authority with respect to packaging of articles covered by the bill is comparable to that provided with respect to other articles by the Fair Packaging and Labeling Act (Public Law 89–755).

SECTION 7

This section would strengthen the principal prohibitory section of the act by—

(*a*) specifically prohibiting the slaughtering of animals or preparation of articles, specified in the bill, for commerce, except in compliance with the act;

(*b*) prohibiting sale, transportation, and other specified transactions, in commerce, with respect to meat and the other specified articles capable of use as human food if they are adulterated or misbranded or have not been inspected and passed as required by title I. (The present act contains similar prohibitions on distribution in interstate or foreign commerce of noninspected articles which would be repealed.)

by the States and other jurisdictions as contemplated by this Act are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

SECTION 3. That hereafter, for the purpose of preventing the use in [interstate or foreign] commerce, as hereinafter provided, of meat and meat food products which are [unsound, unhealthful, unwholesome, or otherwise unfit for human food] *adulterated*, [the Secretary of Agriculture, at his discretion, may] *the Secretary shall* cause to be made, by inspectors appointed for that purpose, an examination and inspection of all [cattle, sheep, swine, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in [interstate or foreign] commerce; and all [cattle, swine, sheep, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other [cattle, sheep, swine, or goats] *cattle, sheep, swine, goats, horses, mules, or other equines*, and when so slaughtered, the carcasses of said [cattle, sheep, swine, or goats] *cattle, sheep, swine, goats, horses, mules, or other equines* shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary [of Agriculture] as herein provided for.

SEC. 4. That for the purposes hereinbefore set forth the Secretary [of Agriculture] shall cause to be made by inspectors appointed for that purpose, as hereinafter provided, a post-mortem examination and inspection of the carcasses and parts thereof of all [cattle, sheep, swine, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* to be prepared [for human consumption] at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia [for transportation or sale] as articles of [interstate or foreign] commerce *which are capable of use as human food;* and the carcasses and parts thereof of all such animals found to be [sound, healthful, wholesome, and fit for human food] *not adulterated* shall be marked, stamped, tagged, or labeled as "Inspected and Passed;" and said inspectors shall label, mark, stamp, or tag as "Inspected and Condemned," all carcasses and parts thereof of animals found to be [unsound, unhealthful, unwholesome, or otherwise unfit for human food] *adulterated;* and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary [of Agriculture] may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become [unsound, unhealthful, unwholesome, or in any way unfit for human food] *adulterated* and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be [unsound, unhealthful, unwholesome, or otherwise unfit for human food] *adulterated*, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary [of

Exhibit 3

Senate Report

Calendar No. 785

90TH CONGRESS, 1st Session | SENATE | REPORT No. 799

FEDERAL MEAT INSPECTION ACT

NOVEMBER 21, 1967.—Ordered to be printed

Mr. MONTOYA, from the Committee on Agriculture and Forestry, submitted the following

REPORT

[To accompany S. 2147]

The Committee on Agriculture and Forestry, to which was referred the bill (S. 2147) to clarify and otherwise amend the Meat Inspection Act, to provide for cooperation with appropriate State agencies with respect to State meat inspection programs, and for other purposes, having considered the same, reports favorably thereon with amendments and recommends that the bill as amended do pass.

SHORT EXPLANATION

This bill would amend the Federal Meat Inspection Act to—

(1) Add a new title III (i) authorizing Federal assistance (including grants) to State meat inspection programs, such assistance not to exceed 50 percent of the cost of the cooperative program; (ii) extending the Federal program to intrastate transactions in States which request such extension or fail to develop adequate State systems; and (iii) providing immediate authority to cover intrastate plants producing adulterated products which endanger the public where the State does not remove such danger.

(2) Extend the Federal program to commerce wholly within the District of Columbia or within any territory not having a legislative body (new sec. 1(h));

(3) Add a new title II (A) prohibiting commerce in animal products not intended for human use unless denatured, properly identified as not intended for human use, or naturally inedible; (B) providing for recordkeeping by certain slaughterers and handlers; registration of certain handlers; and regulation of certain handlers of dead, dying, disabled, or diseased animals and their products (including in each case those engaged in intrastate commerce if not regulated by State law);

85-010—67——1

(s) *Official mark*, (t) *official inspection legend*, (u) *official certificate*, (v) *official device.*—These terms are used in the provisions prohibiting forgery and similar offenses (sec. 8 of the bill) and the definitions would require them to be prescribed by regulation. These terms are not used in the present act.

New section 2 contains the legislative finding of the propriety of regulation and cooperation as provided in the bill to prevent and eliminate burdens on interstate and foreign commerce. This section supports the provisions of the bill which affect intrastate commerce.

Section 3. Mandatory ante mortem inspection

This section would not result in any change in the program. It would make a nonsubstantive drafting change by deleting "interstate or foreign" before "commerce" in sections 3 through 23 of title I of the Federal Meat Inspection Act, in view of the definition of "commerce" in section 1 of this bill. It also would make ante mortem inspection mandatory and change the reference to "Secretary of Agriculture" throughout title I of the act to "Secretary," in view of the definition of "Secretary" in section 1 of this bill. While under the existing law ante mortem inspection is discretionary insofar as the Secretary is concerned, it is mandatory insofar as the industry is concerned. The Secretary has exercised his discretion to require ante mortem inspection. Removing the Secretary's discretion therefore makes no change in the existing program.

(Sec. 3 of the act, which would be amended by this section of the bill, would also be amended by secs. 1, 12(a), and 12(b) of the bill. Those sections give it a section number, extend it to equines, and substitute "adulterated" for "unsound, unhealthful, unwholesome, or otherwise unfit for human food".)

Section 4. "Capable of use as human food"

This section would make it clear that the post mortem inspection provisions of the act apply to articles "capable of use as human food" rather than merely to those intended for transportation or sale for such use. This would make enforcement easier by eliminating any need to prove intention as to use for human food. The term "capable of use as human food" would be defined by section 1(k) of the act, as amended by section 2 of the bill to exclude denatured or naturally inedible articles or articles properly identified as not for human food.

(Sec. 4 of the act, which would be amended by this section of the bill, would also be amended by sections 1, 3, and 12. Those sections would give it a section number, omit "of Agriculture" in the phrase "Secretary of Agriculture", omit "interstate or foreign" in the phrase "interstate or foreign commerce", extend the section to equines and substitute "adulterated" for language having generally similar meaning.)

Section 5. Entry of materials into inspected plants

This section would clarify the authority of the Secretary of Agriculture to restrict entry of carcasses, parts thereof, meat and meat food products, and other materials into establishments that are federally inspected under title I to assure that such entry will be allowed only when consistent with the purposes of the act. This would clarify his authority to exclude uninspected carcasses or other meats or meat products not in clear compliance with the act (including

(r) The terms "pesticide chemical", "food additive", "color additive", and "raw agricultural commodity" shall have the same meanings for purposes of this Act as under the Federal Food, Drug, and Cosmetic Act.

(s) The term "official mark" means the official inspection legend or any other symbol prescribed by regulations of the Secretary to identify the status of any article or animal under this Act.

(t) The term "official inspection legend" means any symbol prescribed by regulations of the Secretary showing that an article was inspected and passed in accordance with this Act.

(u) The term "official certificate" means any certificate prescribed by regulations of the Secretary for issuance by an inspector or other person performing official functions under this Act.

(v) The term "official device" means any device prescribed or authorized by the Secretary for use in applying any official mark.

SEC. 2. Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this Act are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this Act are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

SEC. 3. That hereafter, for the purpose of preventing the use in [interstate or foreign] commerce, as hereinafter provided, of meat and meat food products which are [unsound, unhealthful, unwholesome, or otherwise unfit for human food] *adulterated*, [the Secretary of Agriculture, at his discretion, may] *the Secretary shall* cause to be made, by inspectors appointed for that purpose, an examination and inspection of all [cattle, sheep, swine, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in [interstate or foreign] commerce; and all [cattle, swine, sheep, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other [cattle, sheep, swine, or goats] *cattle, sheep, swine, goats, horses, mules, or other equines*, and when so slaughtered, the carcasses of said [cattle, sheep, swine, or goats] *cattle, sheep, swine, goats, horses, mules, or other equines* shall be subject to a careful exami-

nation and inspection, all as provided by the rules and regulations to be prescribed by the Secretary [of Agriculture] as herein provided for.

SEC. 4. That for the purposes hereinbefore set forth the Secretary [of Agriculture] shall cause to be made by inspectors appointed for that purpose, as hereinafter provided, a post-mortem examination and inspection of the carcasses and parts thereof of all [cattle, sheep, swine, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* to be prepared [for human consumption] at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia [for transportation or sale] as articles of [interstate or foreign] commerce *which are capable of use as human food;* and the carcasses and parts thereof of all such animals found to be [sound, healthful, wholesome, and fit for human food] *not adulterated* shall be marked, stamped, tagged, or labeled as "Inspected and Passed;" and said inspectors shall label, mark, stamp, or tag as "Inspected and Condemned," all carcasses and parts thereof of animals found to be [unsound, unhealthful, unwholesome, or otherwise unfit for human food] *adulterated;* and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary [of Agriculture] may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become [unsound, unhealthful, unwholesome, or in any way unfit for human food] *adulterated* and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be [unsound, unhealthful, unwholesome, or otherwise unfit for human food] *adulterated,* it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary [of Agriculture] may remove inspectors from any establishment which fails to so destroy any such condemned carcass or part thereof.

SEC. 5. The foregoing provisions shall apply to all carcasses or parts of carcasses of [cattle, sheep, swine, and goats] *cattle, sheep, swine, goats, horses, mules, and other equines* or the meat or meat products thereof which may be brought into any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and such examination and inspection shall be had before the said carcasses or parts thereof shall be allowed to enter into any department wherein the same are to be treated and prepared for meat food products; and the foregoing provisions shall also apply to all such products which, after having been issued from any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, shall be returned to the same or to any similar establishment where such inspection is maintained. *The Secretary may limit the entry of carcasses, parts of carcasses, meat and meat food products, and other materials into any establishment at which inspection under this title is maintained, under such conditions as he may prescribe to assure that allowing the entry of such articles into such inspected establishments will be consistent with the purposes of this Act.*

SEC. 6. That for the purposes hereinbefore set forth the Secretary [of Agriculture] shall cause to be made by inspectors appointed for that purpose an examination and inspection of all meat food products

Exhibit 4

Administrative Record Excerpts

PART I – BACKGROUND

This Compliance Program was developed to provide a cohesive framework for the Field to use that would include inspectional priorities, helpful technical information, and resources to facilitate the investigation of residue violations routinely reported to the Food and Drug Administration (FDA) by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). To protect consumers from potentially harmful residues in the food that they eat it is important that inspections are conducted to determine the cause of the illegal drug residues and to develop data descriptive of on-farm practices of management and animal drug use for program decision support, identification of educational needs, and policy development. This program also provides guidance for enforcement measures.. The Federal Food, Drug, and Cosmetic Act (the Act)(21 U.S.C. 321(f)) defines food as "(1) articles used for food or drink for man or other animals…and (3) articles used for components of any such article." (Section 201(f)). Food-producing animals and fish, even though not in their final, edible form, have been held to be food under the statute United States v. Tomahara Enterprises Ltd., Food Drug Cosm. L. Rep. (CCH) 38,217 (N.D.N.Y. 1983) (live calves intended as veal are food) and United States v. Tuente Livestock, 888 F. Supp. 1416, 1423-26 (S.D. Ohio 1995) (live hogs are food). More generally, courts have long held that unprocessed or unfinished articles are or can be food. *See* Otis McAllister & Co. v. United States, 194 F.2d 386, 387 (5th Cir. 1952) and cases cited there (unroasted coffee beans are food). Thus, live animals raised for food are "food" under the Act.

Tissue residue investigations may reveal:

- the illegal sale of veterinary prescription drugs
- the illegal use of bulk drugs
- the extra-label use of drugs (which includes inadequate pre-slaughter withdrawal period)
- cross-contamination of animal feeds due to poor Good Manufacturing Practices (GMPs) (21 CFR Parts 225 or 226)
- failure to follow good animal husbandry practices
- the misuse of drugs in medicated animal feeds
- the marketing of treated/medicated animals intended for rendering purposes being diverted to slaughter for human consumption
- inadequate animal identification

Protection of the public by assuring a safe meat and poultry supply is a responsibility shared by the USDA Food Safety and Inspection Service (FSIS), the Grain Inspection, Packers and Stockyards Administration (GIPSA), the Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), The FSIS exercises supervision over the slaughter and processing of meat and poultry products in federally inspected

establishments and is responsible for the safety of these food products. FSIS reports violative residues of drugs, and both violative and non-violative reisidues of pesticides, and other contaminants in meat and poultry to FDA for follow-up.

The GIPSA works closely with FSIS in regulating animal marketing practices. GIPSA is an enforcement agency within USDA charged with enforcing the Packers and Stockyards Act of 1921 (7 U.S.C. §181) through economic regulation. GIPSA has also assisted FDA in securing producer identification when sales are through auction barns or dealers.

A final rule on swine identification became effective on November 14, 1988. All swine in interstate commerce must be identified and records concerning identification must be maintained. USDA (APHIS and FSIS) is responsible for enforcement. (53 FR 40378, October 14, 1988).

The EPA establishes the tolerances for pesticide residues in meat and poultry. FDA enforces these tolerances.

FDA is responsible for the approval of new animal drugs, including the establishment of tolerances for residues of those drugs in edible tissues. FDA conducts investigations of FSIS-reported residues to determine the party responsible for causing the tissue residue violation and the party responsible for introducing the adulterated food into interstate commerce. The results of FDA investigations have shown that, in most instances, the animal producer is primarily responsible for the illegal drug residues because of failure to comply with drug withdrawal times, other label warnings, use of contaminated animal feeds, use of drugs for unapproved purposes, and employing poor animal husbandry practices. Investigations may also lead to other individuals such as a hauler, buyer, dealer, auction barn, veterinarian, or slaughter house.

FDA has the responsibility to ensure the safety of the seafood supply. In 1995, FDA published the final HACCP (Hazard Analysis and Critical Control Points) regulations for seafood processors (53 FR 40378, December 18, 1995) (21 CFR Parts 123 and 124). The final rule became effective on December 18, 1997. Primary processors of aquaculture products are responsible for ensuring that their HACCP Plans address systems for drug residue control. The Center for Food Safety and Applied Nutrition (CFSAN) issued a Compliance Program Guidance Manual (7304.018), Chemotherapeutics in Seafood, in FY 2002 outlining procedures for sampling aquaculture products to be tested for drug residues. This compliance program addresses sampling of product from both domestic and imported sources.

In 1994, Congress passed legislation that would allow veterinarians to prescribe drugs in a manner inconsistent with the approved new animal or new human drug labeling. This act is called the Animal Medicinal Drug Use Clarification Act (AMDUCA)(21 U.S.C. §360b(a)) and the regulations that implement AMDUCA are published in Title 21 Code of Federal Regulations Part 530. These regulations describe the specific conditions under which extralabel use is permitted.

Actions of FSIS have been categorically excluded from the preparation of an EA or EIS unless the Administrator determines that an action may have a significant environmental effect (7 CFR 1b.4). The Department has long determined that FSIS' programs and activities would have no individual or cumulative effect on the human environment.

The inspection laws mandate that FSIS provide inspection as long as the establishment complies with the statutes' requirements and the Agency's regulations. A Grant of Inspection from FSIS differs from licenses, such as the nuclear reactor licenses issued by the U.S. Nuclear Regulatory Commission (NRC), because the FMIA does not give FSIS permitting authority over the construction of facilities like the Atomic Energy Act (42 U.S.C. 2133 and 2235) and the Federal Power Act (16 U.S.C. 797(e)) give the NRC.

HSUS relies on the case of *The Humane Society of the United States v. Johanns,* 520 F. Supp. 2d 8 (D.D.C. 2007). The Agency believes that case is not applicable to this situation. The *Johanns* case arose after Congress prohibited FSIS, as discussed above, from spending appropriated funds to carry out ante mortem inspection of equines. While the congressional prohibition cited inspection conducted under the FMIA, FSIS subsequently issued a regulation under the Agricultural Marketing Act (AMA) of 1946 that set up a voluntary user fee or fee-for-service program in which FSIS would provide ante-mortem inspection, just as it had done before under the FMIA, for a fee. The District Court ruled that because the regulation did not perpetuate the regulatory status quo, the effects of the horse slaughter operations should have been assessed pursuant to NEPA prior to promulgation of that rule. However, the Agency's view is that FSIS' current activities to potentially resume equine slaughter inspection are occurring under the FMIA, not the AMA, and therefore the situation in the HSUS case is not applicable.

> **Next Steps**: FSIS has evaluated the potential decision to provide equine slaughter inspection and has documented its tentative conclusion in an internal memo. The memo tentatively concludes that FSIS can invoke its categorical exclusion because no unique or potentially significant environmental effects exist compared to the thousands of existing Grants of Inspections for other species.

***Residue Testing*:** As for all amenable species, FSIS will need to verify that any equines slaughtered do not contain an illegal drug residue that would render the meat unfit for human consumption. However, because the Food and Drug Administration (FDA) does not consider equine muscle to be "food," it has not set acceptable daily intake or tolerance levels for residues in equine meat as it has for the other amenable species. Thus, if FSIS finds a drug residue in any equine meat sample, it would not be able to find that the product is not adulterated, and thus the Agency would not be able to apply its mark of inspection to the meat. Importantly, unlike most other livestock, some equines are not raised for human food purposes. Some equines are used for racing and pleasure riding and, consequently, are administered drugs that never were intended for use in food animals (e.g., steroid treatments). Thus, drug residue profiles in equine tissue may be markedly different than for other livestock.

> **Next Steps**: To test equine meat for the presence of drug residues, the Agency intends to validate the methods that it uses to test other amenable species for use on equine meat. The equine residue testing data that the Agency developed from 1983 through 2007 (see attachment 1) suggests that many of the compounds likely to be used in equines fit for use as human food mirror to a large extent those for other amenable species. These data

from that period show that the majority of violations involved antibiotics such as Streptomycin (59 violations in 2000, 35 in 1999); Penicillin (9 violations in 2000, 8 in 1999); and Chlortetracycline, Gentamicin, and Oxytretatratcycline, among others. The remaining violations included various sulfa compounds, pesticides, and antiparasitic drugs.

FSIS has started to validate several new methods for equine tissue. A comprehensive residue testing program could be implemented by the end of the current calendar year. However, implementing validated lab methods for hormones and tranquilizers in equine tissue will not occur until 2014.

Petition Issues: While resolving these technical issues is critical to the development of any inspection system, the decision on how to respond to the HSUS petition will likely determine what type of inspection system FSIS would seek to implement and when. HSUS has petitioned FSIS to ban equine slaughter because, the petition asserts, drug use is so widespread in the United States that it will be virtually impossible for FSIS to establish a residue testing program that will ensure the safety of equine meat. Specifically, the petition requests that FSIS engage in rulemaking to prevent the risk that consumers of equine meat will have painful or prolonged adverse reactions or drug side effects or contract diseases after they have eaten the meat from these equines; and to ensure that proper controls are in place to prevent these equines from being slaughtered for food. HSUS highlights 42 compounds administered to equines that it believes pose food safety risks. FSIS has developed a plan for implementing testing for the majority of these compounds (see attachment 2).

HSUS argues that the only way to ensure the safety of equine meat is to establish a system that captures the history of drug use on each animal, similar to that employed by the European Union. Canada also has an equine slaughter system that may provide a model.

The EU System: The EU recently introduced the following requirements for equines intended for human food:

- The creation of a system of identity verification for equines intended for human food;
- A prohibition of anabolic steroids, or a system of segregating equines that have been treated with steroids;
- A system providing that all equines have lifetime treatment records documenting all substances used for treatments;
- Compliance with required 6-month withdrawal periods for veterinary medical products administered to equines; and
- The creation of a risk-based program to control the use of veterinary medical products and substances banned for use in the EU

The Canadian System: The Canadian Food Inspection Agency (CFIA) maintains a domestic equine slaughter inspection program that includes traceability and chemical residue testing. This program meets the EU requirements discussed above.

All Canadian equine slaughter establishments must keep complete identity and medical records of all animals presented for slaughter, either by an Equine Information Document (EID) or the Equine Lot Program (ELP), which is similar to the U.S. EV program. EID contains the animal description, 6-month drug history, picture ID/or other means of identification of the animal, and medical history. This document must accompany the animal at time of ownership transfer. In the ELP, an owner of a group or groups of animals may present a group declaration instead of individual EIDs. CFIA audits the ELP annually. According to CFIA, the advantage of ELP is that the owner is not required to provide a full narrative description of each individual animal, paperwork is reduced, and CFIA deems these animals under this program to be of lesser food safety risk.

CFIA has provided a list of drugs that food-producing animals should not receive throughout life and a list of drugs that should be not given during last 6 months of life. FSIS has not identified a mechanism used by CFIA to determine whether the prohibited drugs were ever given during an animal's life, as CFIA only reviews records from the last 6 months. However, CFIA has informed FSIS that Canada is working to develop a lifetime identity and traceability system for equine slaughter.

CFIA operates a residue testing program for equines based on EU requirements (EU Directive 96/23), and equines are also tested for Trichinae using a digestion method.

The question thus becomes whether, assuming that FSIS validates the methods that it intends to use on equine meat, and assuming that none of the questions discussed above present an insurmountable obstacle, FSIS could appropriately apply its mark of inspection to equine meat without requiring the type of documented drug use history required by the EU or Canada, or should it institute rulemaking to require such a history? There are two factors that bear on this question. First, once validated, will the tests that FSIS intends to employ be broad enough so that FSIS can confidently assert that a negative result in this testing ensures that no drugs have been illegally used on the equine? There is some sentiment in the FSIS labs that the answer to this question is yes. There is a belief that the presence of a residue of any drug likely to be illegally used in equines would be discovered by one of the tests that the Agency is validating for equine meat. FSIS would likely need to confirm this view with FDA should there be tentative acceptance of it.

The second factor is largely political. FSIS is already seen in some quarters in Congress as dragging its feet on the equine slaughter issue. To require a passport-type approach like that of the EU, FSIS would have to engage in rulemaking. Such rulemaking would likely take at least 2 years. Some are sure to argue that such a passport is unnecessary because FSIS operated the equine slaughter program prior to 2006, and prior to the EU's new requirements adopted in 2009, without requiring such information. Another factor to be considered is the possibility of punitive congressional action if FSIS fails to institute an equine slaughter program.

Finally, the Agency needs to consider the argument that equines are an amenable species under the FMIA, and therefore FSIS has no choice but to institute an equine slaughter and further

processing program. Under this argument, the fact that drug use is widespread in equines is essentially irrelevant. FSIS needs to have an inspection program for equines even if every equine presented for slaughter is condemned for a drug residue. It is up to the producers and the slaughter plant whether they wish to risk the investment that they have in the equines. It is FSIS's obligation to provide the slaughter program and take appropriate steps to ensure food safety.

RECOMMENDED OPTIONS:

FSIS expects to make recommendations on how to respond to the HSUS petition by late October. Assuming the technical issues discussed above (inspection processes, inspector training, environmental impacts, and residue methods) are satisfactorily resolved, FSIS could:

Option 1: Accept the petition and initiate rulemaking to require lifetime medical history for horses slaughtered for human consumptions on the grounds that equines, especially since 2006, have not been raised as food animals and have thus been administered a wide variety of drugs unfit for human consumption. To give the Agency time to develop rulemaking and formulate a process to implement a system that is EU-equivalent, as the petition recommends, FSIS would delay moving forward with implementing a system for equines that is based on lab methods for other amenable species. FSIS would need to initiate rulemaking to establish a system that captures the history of drug use on each animal, including lifetime treatment records, or simply request public input on the issue.

> *Pro*: This approach could both ensure that equine meat is safe, and work toward meeting new requirements implemented in 2009 by the EU.
>
> *Con*: First, developing and implementing such a system would require substantially more time, planning, and resources. Rulemaking would require at least 2 years. Second, this approach would be contrary to the one applied to all other livestock, for which the existing drug surveillance testing program is sufficient. Third, implementing validated lab methods for hormones and tranquilizers in equine tissue will not occur until 2014. Finally, establishing such an animal identification system, as required by the EU for export of equine meat, should come as a broader government-wide decision, not simply for one species.

Option 2: Deny the HSUS petition on grounds that it is not compelling as to why equine slaughter and processing are unique versus other livestock, and because the FSIS surveillance program for drug residues in horses should be sufficient to protect public health. When all lab methods relevant to equine tissue are validated, FSIS would proceed with implementing a residue program that parallels the one used for other amenable species. Establishments seeking to export to the EU would still need to separately meet EU requirements, and FSIS could work with the Agricultural Marketing Service to develop a voluntary, fee-for-service Export Verification (EV)-style program to verify that those requirements were met before export. AMS would be responsible for reviewing and approving companies as eligible suppliers of equine

meat and for maintaining approved supplier and products lists.

Pro: Implementing a system based on that used for other amenable species is logically consistent with FSIS' overall approach to residue testing. Once lab methods are fully developed, FSIS labs will be capable of testing for the compounds of concern in the petition. An EV program would allow establishments to export to the EU, and potentially other foreign markets.

Con: Many stakeholders, including the general public, may perceive that using a system based on other amenable species is not sufficient to protect the public health, potentially leading to further stakeholder and congressional action. Developing and implementing an EV program would require substantial time and resources.

Option 3: Postpone ruling on the merits of the petition or implementing inspection of horse slaughter or processing on the grounds that the petition has raised sufficient concern about the safety of equine meat that FSIS must further evaluate residue testing for equine tissue. FSIS would need to determine first, whether or not residues are present, and second, if the residues that are present have a lasting, harmful effect. While implementing validated testing methods for equine tissue would determine residue presence, FSIS would consult with FDA to determine whether or not FDA would find that certain drugs administered to equines have a lasting, harmful effect on the muscle tissue.

Pro: Further evaluating residue presence in equine tissue would provide evidence to substantiate or refute stakeholder claims that there is a public health risk associated with consumption of equine meat.

Con: FSIS could be seen as not following congressional direction and again delaying the process of developing a system for equine slaughter and further processing. FSIS would likely need to deflect persistent efforts from all interested stakeholders to change the Agency's course in the meantime. Industry would be indefinitely prevented from proceeding with equine slaughter. Acknowledging the uncertainty of the concerns raised in the petition would also likely open FSIS' existing residue testing program for all other species to similar scrutiny.

DECISION BY THE UNDER SECRETARY:

Option 1 _____

Option 2 _____

Option 3 _____

Discuss with me _____

Reviewed by _____

Date _____

Appendix 1

Updated - 8/8/2012 PB

FSIS National Residue Program - Historical Data on Equine Residue Testing

YEAR	Monitoring Program				Surveillance Samples		
1983	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Sulfadimethoxine	96	0	0	8	0	0
	Sulfamethazine	96	3	4	8	2	0
	Sulfathizole	96	1	0	8	0	0
	Sulfabromomethazine	96	0	0	8	0	0
	Penicillin	94	0	1	8	0	0
	Streptomycin	94	0	0	8	0	1
	Tetracycline	94	0	0	8	0	0
	Erythromycin	94	0	0	8	0	0
	Neomycin	94	0	0	8	0	0
	Oxytetracycline	94	0	0	8	0	0
	Chlortetracycline	94	0	0	8	0	0
	Chloramphenicol	11	0	0			

YEAR	Monitoring Program				Surveillance Samples		
1984	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	343	0	0	30	0	0
	Benzene Hydrochloride	343	62	1	30	0	0
	Chlordane	343	4	1	30	1	0
	Dieldrin	343	25	1	30	5	0
	DDT and metabolities	343	69	0	30	5	0
	Endrin	343	2	0	30	1	0
	Heptachlor	343	32	0	30	13	0
	Lindane	343	3	0	30	0	0
	Methoxychlor	343	1	0	30	0	0
	Toxaphene	343	1	0	30	0	0
	PCB	343	0	0	30	0	0
	Hexachrolobenzene	343	53	0	30	0	0
	Mirex	343	0	0	30	0	0
	Strobane	343	0	0	30	0	0
	Nonachlor	343	0	0	30	0	0
	Penicillin	281	0	1	6	0	0
	Streptomycin	281	0	1	6	0	0
	Tetracycline	281	0	0	6	0	0
	Erythromycin	281	0	0	6	0	0
	Neomycin	281	0	0	6	0	0
	Oxytetracycline	281	0	0	6	0	0
	Chlortetracycline	281	0	0	6	0	0
	Gentamicin	281	0	0			
	Sulfathoxypyridazine	24	0	0			
	Sulfachloropyridazine	76	0	0			
	Sulfadimethoxine	102	0	0	1	0	0
	Sulfamethazine	102	0	3	1	1	0
	Sulfamethoxypyridazine	24	0	0			
	Sulfathiazole	102	0	1	1	0	0
	Sulfaquinoxaline	102	0	0			
	Sulfabromomethazine	102	0	0	1	0	0
	Sulfapyridine	102	0	0	1	0	0
	Chloraphenicol	115	0	0			
	Fenbendazole	109	0	1			

YEAR	Monitoring Program				Surveillance Samples		
1985	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	313	0	0	10	0	0
	Benzene Hydrochloride	313	3	0	10	0	0
	Chlordane	313	3	0	10	0	0
	Dieldrin	313	2	0	10	0	0
	DDT and metabolities	313	35	1	10	0	0
	Endrin	343	0	0	10	0	0
	Heptachlor	313	5	0	10	0	0
	Lindane		1	0	10	0	0
	PCB				10	1	0
	Mirex	313	1	0	10	0	0
	Penicillin	339	0	1	5	0	0
	Streptomycin	339	0	1	5	0	0
	Tetracycline	339	0	0	5	0	0
	Tylosin	339	0	0	5	0	0
	Erythromycin	339	0	0	5	0	0
	Neomycin	339	0	0	5	0	0
	Oxytetracycline	339	0	0	5	0	0
	Chlortetracycline	339	0	0	5	0	0
	Gentamicin	339	0	0	5	0	0
	Licomycin	339	0	0	5	0	0
	Novobiocin	339	0	0	5	0	0
	Virginiamycin	339	0	0	5	0	0
	Sulfathoxypyridazine	105	0	0			
	Sulfachloropyridazine	105	0	0			
	Sulfadimethoxine	105	0	0			
	Sulfamethazine	105	0	1			
	Sulfamethoxypyridazine	105	0	0			
	Sulfathiazole	105	0	0			
	Sulfaquinoxaline	105	0	0			
	Sulfabromomethazine	105	0	0			
	Sulfapyridine	105	0	0			
	OPs (Screen) /Parathion				1	1	0

OP Screen: Coumaphos, Dichlrvos, Diazinon, Ethion, Malathion, Parathion, Ronnel, Cruomate, Trichlorfon, Methyl Parathion, Dioathion

YEAR	Monitoring Program				Surveillance Samples		
1986	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	108	0	0			
	Benzene Hydrochloride	108	5	0			
	Chlordane	108	0	0			
	Dieldrin	108	9	1			
	DDT and metabolities	108	39	0			
	Endrin	108	0	0			
	Heptachlor	108	16	0			
	Lindane	108	1	0			
	Methoxychlor	108	0	0			
	Toxaphene	108	0	0			
	PCB	108	0	0			
	HCB	108	5	0			
	Mirex	108	0	0			
	Strobane	108	0	0			
	Nonachlor	108	0	0			
	Penicillin	111	0	3	20	0	0
	Streptomycin	111	0	2	20	0	3
	Tetracycline	111	0	0	20	0	0
	Tylosin	111	0	0	20	0	0
	Erythromycin	111	0	0	20	0	0
	Neomycin	111	0	0	20	0	1
	Oxytetracycline	111	0	0	20	0	0
	Chlortetracycline	111	0	0	20	0	0
	Gentamicin	111	0	0	20	0	0
	Licomycin	111	0	0	20	0	0
	Novobiocin	111	0	0	20	0	0
	Virginiamycin	111	0	0	20	0	0
	Sulfathoxypyridazine	111	0	0			
	Sulfachloropyridazine	111	0	0			
	Sulfadimethoxine	111	0	0			
	Sulfamethazine	111	0	0			
	Sulfamethoxypyridazine	111	0	0			
	Sulfathiazole	111	0	0			
	Sulfaquinoxaline	111	0	0			
	Sulfabromomethazine	111	0	0			
	Sulfadiazine	111	0	1			
	Sulfapyridine	111	0	0			
	OP (Screen)	106	0	0			

YEAR	Monitoring Program				Surveillance Samples		
1987	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	337	0	0			
	Benzene Hydrochloride	337	15	0			
	Chlordane	337	4	3			
	Dieldrin	337	17	0			
	DDT and metabolities	337	68	0			
	Endrin	337	0	0			
	Heptachlor	337	30	1			
	Lindane	337	4	0			
	Methoxychlor	337	1	0			
	Toxaphene	337	0	0			
	PCB	337	0	0			
	HCB	337	44	0			
	Mirex	337	0	0			
	Strobane	337	0	0			
	Nonachlor	337	0	0			
	Penicillin	338	0	3	25	0	4
	Streptomycin	338	0	6	25	0	4
	Tetracycline	338	0	0	25	0	0
	Tylosin	338	0	0	25	0	0
	Erythromycin	338	0	0	25	0	0
	Neomycin	338	0	0	25	0	0
	Oxytetracycline	338	0	0	25	0	0
	Chlortetracycline	338	0	0	25	0	1
	Gentamicin	338	0	0	25	0	0
	Licomycin	338	0	0	25	0	0
	Novobiocin	338	0	0	25	0	0
	Virginiamycin	338	0	0	25	0	0
	Sulfathoxypyridazine	134	0	0			
	Sulfachloropyridazine	134	0	0			
	Sulfadimethoxine	134	0	0			
	Sulfamethazine	134	0	0			
	Sulfamethoxypyridazine	134	0	0			
	Sulfathiazole	134	0	0			
	Sulfaquinoxaline	134	0	0			
	Sulfabromomethazine	134	0	0			
	Sulfadiazine	134	0	0			
	Sulfapyridine	134	0	0			
	Arsenic	341	27	0			

YEAR	Monitoring Program				Surveillance Samples		
1988-89	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	300		0			
	Chlorinated OPs	299		0			
	Ivermectin	305		1			
	Penicillin	305		0	552		5
	Streptomycin	305		3	552		1
	Tetracycline	305		0	552		1
	Tylosin	305		0			
	Erythromycin	305		0	552		0
	Neomycin	305		0	552		0
	Oxytetracycline	305		0	552		1
	Chlortetracycline	305		0	552		0
	Gentamicin	305		0	552		0
	Sulfathoxypyridazine	306		0			
	Sulfachloropyridazine	306		0			
	Sulfadimethoxine	306		0			
	Sulfamethazine	306		2			
	Sulfamethoxypyridazine	306		0			
	Sulfathiazole	306		0			
	Sulfaquinoxaline	306		0			
	Sulfabromomethazine	306		0			
	Sulfadiazine	306		0			
	Sulfapyridine	306		0			
	Arsenic	304		1			

YEAR	Monitoring Program				Surveillance Samples		
1990	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	298		0			
	Chlorinated OPs	298		0			
	Ivermectin	310		0			
	Penicillin	313		1	512		14
	Streptomycin	313		17	512		8
	Tetracycline	313		0	512		
	Tylosin	313		0			
	Erythromycin	313		0	512		
	Neomycin	313		0	512		
	Oxytetracycline	313		0	512		
	Chlortetracycline	313		0	512		
	Gentamicin	313		0	512		1
	Sulfathoxypyridazine	313		o			
	Sulfachloropyridazine	313		0			
	Sulfadimethoxine	313		0			
	Sulfamethazine	313		0			
	Sulfamethoxypyridazine	313		0			
	Sulfathiazole	313		0			
	Sulfaquinoxaline	313		0			
	Sulfabromomethazine	313		0			
	Sulfadiazine	313		0			
	Sulfapyridine	313		0			
	Arsenic	310		0			

YEAR	Monitoring Program				Surveillance Samples		
1991	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	106		0			
	Chlorinated OPs	106		0			
	Ivermectin	101		3			
	Penicillin	100		0	708		17
	Streptomycin	100		2	708		17
	Tetracycline	100		0	708		
	Tylosin	100		0			
	Erythromycin	100		0	708		
	Neomycin	100		0	708		
	Oxytetracycline	100		0	708		
	Chlortetracycline	100		0	708		
	Gentamicin	100		0	708		3
	Sulachloropyrazine	106		0			
	Sulfachloropyridazine	106		0			
	Sulfadimethoxine	106		0			
	Sulfamethazine	106		0			
	Sulfamethoxypyridazine	106		0			
	Sulfathiazole	106		0			
	Arsenic	101		0			

YEAR	Monitoring Program				Surveillance Samples		
1992	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	98		1 (coumaphos)			
	Ivermectin	94		2			
	Penicillin	101		0	1008		25
	Streptomycin	101		0	1008		19
	Tetracycline	101		0	1008		0
	Tylosin	101		0			
	Erythromycin	101		0	1008		0
	Neomycin	101		0	1008		0
	Oxytetracycline	101		0	1008		1
	Chlortetracycline	101		0	1008		0
	Gentamicin	101		0	1008		0
	Sulachloropyrazine	103		0			
	Sulfachloropyridazine	103		0			
	Sulfadimethoxine	103		0	1008		1
	Sulfamethazine	103		0	1008		1
	Sulfamethoxypyridazine	103		0			
	Sulfathiazole	103		0			
	Arsenic	94		0			
	Benzimidazoles	99		0			

YEAR	Monitoring Program				Surveillance Samples		
1993	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	425		1 coumaphos 1 dieldrin 1 PCB	Enforcement		11 coumaphos
	Ivermectin	405		0			
	Penicillin	309		2	725		19
	Streptomycin	309		10			8
	Tetracycline	309		0			0
	Tylosin	309		0			0
	Erythromycin	309		0			0
	Neomycin	309		0			0
	Oxytetracycline	309		0			4
	Chlortetracycline	309		0			0
	Gentamicin	309		0			2
	Sulachloropyrazine	306		0			0
	Sulfachloropyridazine	306		0			0
	Sulfadimethoxine	306		1			6
	Sulfamethazine	306		2			0
	Sulfamethoxypyridazine	306		0			0
	Sulfathiazole	306		0			0
	Arsenic	0					

YEAR	Monitoring Program				Surveillance Samples		
1994	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	217		0			
	Ivermectin						
	Penicillin	0			421		8
	Streptomycin	0			421		4
	Tetracycline	0					0
	Tylosin	0					0
	Erythromycin	0					0
	Neomycin	0					0
	Oxytetracycline	0					0
	Chlortetracycline	0					0
	Gentamicin	0			421		1
	Sulachloropyrazine	0					
	Sulfachloropyridazine	0					
	Sulfadimethoxine	0					
	Sulfamethazine	0					
	Sulfamethoxypyridazine	0					
	Sulfathiazole	0					
	Arsenic	0					

YEAR	Monitoring Program				Surveillance Samples		
1995	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COPs screen	507		4 coumaphos	Enforcement		
				1 heptachlor	180 samples		0
	Ivermectin						
	Penicillin	0			318		8
	Streptomycin	0					
	Tetracycline	0					
	Tylosin	0					
	Erythromycin	0					
	Neomycin	0					
	Oxytetracycline	0					
	Chlortetracycline	0					
	Gentamicin	0					
	Sulfonamides	0					

YEAR 1996	Program				Surveillance Samples		
	Compounds	Monitoring Analyzed/V	Enforcement Analyzed/V	Violative Compound	# STOP Test/V	# FAST	Violative Componds
	Antibiotics -			**0**	**306/11**		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						**1**
	Penicillin						**8**
	Streptomycin						**2**
	Tetracycline						
	Tylosin						
	Sufonamides -						
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	503/1	53/18	Dieldrin-1			
				Coumaphos-18			
	Trace metals	503	53	none			

Total Horse Slaughter in 1997: 82,025 heads

YEAR	Monitoring Program				Surveillance Samples		
1997	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violations
		Analyzed/V	Analyzed/V	Compounds	Tests/Viol.	Tests/Viol.	Compounds
	Antibiotics -	**386/20**	**0**		**59/1**		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						1
	Penicillin			5			
	Streptomycin			17			
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**234/1**					
	Sulfacloropyridazine						
	Sulfadimethoxine			1			
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	457/5		Dieldrin - 1 Heptachlor - 1 PCB - 2 Phenybutazone - 1			
	Arsenic	87/0					
	Ivermectin	256/1					
	Clenbuterol		1,420				

Total Horse Slaughter in 1998: 68,783 heads

YEAR	Monitoring Program				Surveillance Samples		
1998	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violations
		Analyzed/V	Analyzed/V	Compounds	Tests/Viol.	Tests/Viol.	Compounds
	Antibiotics -	**442/20**	10-0		70/0		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			**6**			
	Streptomycin			**15**			
	Tetracycline						
	Tylosin						
	Sufonamides -	226/0					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	467/0					
	Arsenic	91/0					
	Ivermectin	292/0					

Total Horse Slaughter in 1999: 64,036 heads

YEAR	Monitoring Program				Surveillance Samples		
1999	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**446**			222		
	Bacitracin						
	Chlortetracycline			**2**			
	Erythromycin						
	Flavomycin						
	Gentamicin			**1**			
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline			**1**			
	Penicillin			**8**			**1**
	Streptomycin			**35**			
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**285**					
	Sulfacloropyridazine						
	Sulfadimethoxine			**1**			
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	301		**Phenybutazone**			
				1			

FSIS National Residue Program - Historical Data on Equine Residue Testing

YEAR	Monitoring Program				Surveillance Samples		
2000	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**434**			552		
	Bacitracin						
	Chlortetracycline			**1**			
	Erythromycin						
	Flavomycin						
	Gentamicin			**1**			**1**
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline			**1**			
	Penicillin			**9**			**3**
	Streptomycin			**59**			**2**
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -						
	21 Sulfa compounds			Sulfadimethoxine			
				1			
	CHC/COPs screen	285		**Phenybutazone**			
	21 compound			**1**			
	Avermectin	285		**2**			
	Moxidectin	285					

Total Horse Slaughter in 2003: 50,062 heads

YEAR	Monitoring Program				Surveillance Samples		
2003	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**193**		**0**	**108**	**9**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**199**		**0**			
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**157**		**0**			
	Avermectin	**149**		**0**			
	Moxidectin	**149**		**0**			

Total Horse Slaughter in 2004: 65,200 heads

YEAR	EXPLORATORY Program				Surveillance Samples		
2004	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**15**					
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			2			
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**17**					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**15**		**Phenybutazone**			
				1			
	Avermectin	**17**					
	Moxidectin						

Total Horse Slaughter in 2005: 93,768 heads

YEAR	EXPLORATORY Program				Surveillance Samples		
2005	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**8**			**85**	**30**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			**2**			
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**10**					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**9**		**Phenybutazone**			
				1			
	Avermectin	**7**					
	Moxidectin						

Total Horse Slaughter in 2006: 104,433 heads

YEAR	Monitoring Program				Surveillance Samples		
2006	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	112		0	75	4	0
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	0					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	281		PBDE - 1			
	Avermectin	113		0			
	Moxidectin	113		0			

Total Horse Slaughter in 2007: 29,707 heads

YEAR 2007	Monitoring Program				Surveillance Samples		
	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	0			7	6	0
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -						
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	50		0			
	Avermectin	54		0			
	Moxidectin	54		0			

YEAR 2008	Monitoring Program				Surveillance Samples		
	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	0			0	0	
	Sufonamides -	0					
	CHC/COPs screen	0					
	Avermectin	0					
	Moxidectin	0					

Appendix 2

COMPOUNDS	IMPLEMENTATION						
	2012	2013	2014				
	Current	Next	Hormones	Tranquilizers	Not - Relevant	Other	Comment
1. Acepromazine		X					Add to MRM
2. Acetazolamide		X					Sulfonamide
3. Acriflavin					X		Topical application
4. Glycosaminoglycan						X	Joint medication
5. Altrenogest			X				Hormonal effect
6. Amikacin	X						
7. Antibiotics	X						
8. Antiseptic					X		Topical application
9. Avermectin	X						
10. Boldenone			X				Hormonal effects
11. Butorphanol				X			Pain med
12. Carbadox	X						
13. Ceftiofur	X						
14. Chloramphenicol	X						
15. Copper					X		Topical application
16. Cupric sulfate					X		Topical application
17. Kerosene					X		Topical application
18. Deslorelin			X				Hormonal effect
19. Dexamethasone	X						
20. Diclofenac sodium				X			Pain med
21. Dormosedan				X			Sedative / analgesic
22. Doxycycline		X					Add to MRM
23. Enrofloxacin	X						
24. Eucalyptus oil					X		Topical application
25. Flunixin	X						
26. Furaltadone	X						
27. Furazolidone	X						
28. Gentamicin	X						
29. Hyaluronate						X	Joint disease
30. Isoflurane					X		Gas anesthetic
31. Levothyroxine			X				Thyroid replacement hormone
32. Luprostiol			X				Hormonal effect
33. Methylandrostenediol			X				Hormonal effect
34. Methylprednisolone	X						Prednisone but not

Appendix 2

COMPOUNDS	IMPLEMENTATION						
	2012	2013	2014				
	Current	Next	Hormones	Tranquilizers	Not - Relevant	Other	Comment
and Prednisone							methylprednisolone at this time
35. Moxidectin	X						
36. 3-dicarboximide		X					Dicarboximides are a class of fungicides including vinclozolin and iprodione, which are in the AMS PDP method on GC. These fungicides rapidly turn into 3,5-dichloroaniline in soil. Need to determine the correct analyte of interest.
37. Neomycin	X						
38. Omeprazole						X	Stomach ulcers
39. Phenylbutazone	X						
40. Prallethrin		X					Pyrethroid insecticide in the AMS PDP method on GC
41. Thyrostats	X						
42. Triamcinolone acetonide					X		Topical application
TOTAL	17	5	6	3	8	3	

NRP 2012	17
During NRP 2013	5
During NRP 2014	9
Not applicable	11

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

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JUN 28 2013

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

August 9, 2012

History of residue testing by FSIS in horses

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We currently have records in FSIS for about 25 years of residue testing in horses presented for slaughter at USDA licensed facilities. This data starts from 1983 through 2007, with no further records from 2008 forward. The detailed data has now been captured to indicate the details of the yearly testing and the results.

While no archived records remain as to the reason for selections of the compounds that were tested for in horses, there is enough evidence from the data to indicate the selection of the compounds for horses mirrors that for cattle. This selection is traditionally made by the joint USDA-FDA-EPA Strategic Advisory Team (SAT), that meets at least once a year to guide FSIS towards the compounds to be selected in SAT meeting held in the prior year. The final compound selection is based on a history of use, an official tolerance, availability of regulatory method and appropriate equipment at the FSIS laboratories.

For the years that we could locate the data, there was between 29,707 heads slaughter in 2007, to a maximum of 104,433 heads slaughtered in 2006 under FSIS inspection. Of the compounds detected in violative levels (per FDA guidelines), the most were for antibiotics. Examples include: Streptomycin (59 violations in 2000, 35 in 1999); Penicillin (9 violations in 2000, 8 in 1999); Chlortetracycline, Gentamicin, Oxytretatratcycline, etc.). There are a few violative findings for different sulfa compounds and antiparasitic drugs. There are a few pesticide violations in the 1980's data; however, that is not recorded in the later years of this program. There is evidence however, that some testing was done as "Exploratory", which is defined as a follow-up to intelligence or violative findings for a given compound. In plant residue quick-tests STOP (Swab Test on Premises) and FAST (Field Antibiotic and Sulfa Test) are also recorded for animals, resulting in a few more antibiotic violative findings.

Having worked in the Southwestern Region of FSIS as the Residue Staff Officer in the late 1980's, I have often visited the largest horse slaughter plants in the USA, that slaughter over 1000 animals a week. Most horses arriving appeared healthy, although a few appeared culled, where in-plant residue quick tests (such as the KIS test) would easily screen for residues of any drugs used to enable transporting these animals to the slaughterhouse. In general, I did not note misuse of drugs in horses; historically the occurrence of residues in horses has been less than what we find in the cull dairy cow and the bob veal slaughter facility.

The data mentioned above is attached.

Updated - 8/8/2012 PB

FSIS National Residue Program - Historical Data on Equine Residue Testing

YEAR	Monitoring Program				Surveillance Samples		
1983	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Sulfadimethoxine	96	0	0	8	0	0
	Sulfamethazine	96	3	4	8	2	0
	Sulfathizole	96	1	0	8	0	0
	Sulfabromomethazine	96	0	0	8	0	0
	Penicillin	94	0	1	8	0	0
	Streptomycin	94	0	0	8	0	1
	Tetracycline	94	0	0	8	0	0
	Erythromycin	94	0	0	8	0	0
	Neomycin	94	0	0	8	0	0
	Oxytetracycline	94	0	0	8	0	0
	Chlortetracycline	94	0	0	8	0	0
	Chloramphenicol	11	0	0			

YEAR	Monitoring Program				Surveillance Samples		
1984	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	343	0	0	30	0	0
	Benzene Hydrochloride	343	62	1	30	0	0
	Chlordane	343	4	1	30	1	0
	Dieldrin	343	25	1	30	5	0
	DDT and metabolities	343	69	0	30	5	0
	Endrin	343	2	0	30	1	0
	Heptachlor	343	32	0	30	13	0
	Lindane	343	3	0	30	0	0
	Methoxychlor	343	1	0	30	0	0
	Toxaphene	343	1	0	30	0	0
	PCB	343	0	0	30	0	0
	Hexachrolobenzene	343	53	0	30	0	0
	Mirex	343	0	0	30	0	0
	Strobane	343	0	0	30	0	0
	Nonachlor	343	0	0	30	0	0
	Penicillin	281	0	1	6	0	0
	Streptomycin	281	0	1	6	0	0
	Tetracycline	281	0	0	6	0	0
	Erythromycin	281	0	0	6	0	0
	Neomycin	281	0	0	6	0	0
	Oxytetracycline	281	0	0	6	0	0
	Chlortetracycline	281	0	0	6	0	0
	Gentamicin	281	0	0			
	Sulfathoxypyridazine	24	0	0			
	Sulfachloropyridazine	76	0	0			
	Sulfadimethoxine	102	0	0	1	0	0
	Sulfamethazine	102	0	3	1	1	0
	Sulfamethoxypyridazine	24	0	0			
	Sulfathiazole	102	0	1	1	0	0
	Sulfaquinoxaline	102	0	0			
	Sulfabromomethazine	102	0	0	1	0	0
	Sulfapyridine	102	0	0	1	0	0
	Chloraphenicol	115	0	0			
	Fenbendazole	109	0	1			

YEAR	Monitoring Program				Surveillance Samples		
1985	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	313	0	0	10	0	0
	Benzene Hydrochloride	313	3	0	10	0	0
	Chlordane	313	3	0	10	0	0
	Dieldrin	313	2	0	10	0	0
	DDT and metabolities	313	35	1	10	0	0
	Endrin	343	0	0	10	0	0
	Heptachlor	313	5	0	10	0	0
	Lindane	313	1	0	10	0	0
	PCB				10	1	0
	Mirex	313	1	0	10	0	0
	Penicillin	339	0	1	5	0	0
	Streptomycin	339	0	1	5	0	0
	Tetracycline	339	0	0	5	0	0
	Tylosin	339	0	0	5	0	0
	Erythromycin	339	0	0	5	0	0
	Neomycin	339	0	0	5	0	0
	Oxytetracycline	339	0	0	5	0	0
	Chlortetracycline	339	0	0	5	0	0
	Gentamicin	339	0	0	5	0	0
	Licomycin	339	0	0	5	0	0
	Novobiocin	339	0	0	5	0	0
	Virginiamycin	339	0	0	5	0	0
	Sulfathoxypyridazine	105	0	0			
	Sulfachloropyridazine	105	0	0			
	Sulfadimethoxine	105	0	0			
	Sulfamethazine	105	0	1			
	Sulfamethoxypyridazine	105	0	0			
	Sulfathiazole	105	0	0			
	Sulfaquinoxaline	105	0	0			
	Sulfabromomethazine	105	0	0			
	Sulfapyridine	105	0	0			
	OPs (Screen) /Parathion				1	1	0

OP Screen: Coumaphos, Dichlrvos, Diazinon, Ethion, Malathion, Parathion, Ronnel, Cruomate, Trichlorfon, Methyl Parathion, Dioathion

YEAR	Monitoring Program				Surveillance Samples		
1986	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	108	0	0			
	Benzene Hydrochloride	108	5	0			
	Chlordane	108	0	0			
	Dieldrin	108	9	1			
	DDT and metabolities	108	39	0			
	Endrin	108	0	0			
	Heptachlor	108	16	0			
	Lindane	108	1	0			
	Methoxychlor	108	0	0			
	Toxaphene	108	0	0			
	PCB	108	0	0			
	HCB	108	5	0			
	Mirex	108	0	0			
	Strobane	108	0	0			
	Nonachlor	108	0	0			
	Penicillin	111	0	3	20	0	0
	Streptomycin	111	0	2	20	0	3
	Tetracycline	111	0	0	20	0	0
	Tylosin	111	0	0	20	0	0
	Erythromycin	111	0	0	20	0	0
	Neomycin	111	0	0	20	0	1
	Oxytetracycline	111	0	0	20	0	0
	Chlortetracycline	111	0	0	20	0	0
	Gentamicin	111	0	0	20	0	0
	Licomycin	111	0	0	20	0	0
	Novobiocin	111	0	0	20	0	0
	Virginiamycin	111	0	0	20	0	0
	Sulfathoxypyridazine	111	0	0			
	Sulfachloropyridazine	111	0	0			
	Sulfadimethoxine	111	0	0			
	Sulfamethazine	111	0	0			
	Sulfamethoxypyridazine	111	0	0			
	Sulfathiazole	111	0	0			
	Sulfaquinoxaline	111	0	0			
	Sulfabromomethazine	111	0	0			
	Sulfadiazine	111	0	1			
	Sulfapyridine	111	0	0			
	OP (Screen)	106	0	0			

YEAR	Monitoring Program				Surveillance Samples		
1987	Compounds	# Analyzed	NV Positive	Violations	# tested	NV Positive	Violations
	Aldrin	337	0	0			
	Benzene Hydrochloride	337	15	0			
	Chlordane	337	4	3			
	Dieldrin	337	17	0			
	DDT and metabolities	337	68	0			
	Endrin	337	0	0			
	Heptachlor	337	30	1			
	Lindane	337	4	0			
	Methoxychlor	337	1	0			
	Toxaphene	337	0	0			
	PCB	337	0	0			
	HCB	337	44	0			
	Mirex	337	0	0			
	Strobane	337	0	0			
	Nonachlor	337	0	0			
	Penicillin	338	0	3	25	0	4
	Streptomycin	338	0	6	25	0	4
	Tetracycline	338	0	0	25	0	0
	Tylosin	338	0	0	25	0	0
	Erythromycin	338	0	0	25	0	0
	Neomycin	338	0	0	25	0	0
	Oxytetracycline	338	0	0	25	0	0
	Chlortetracycline	338	0	0	25	0	1
	Gentamicin	338	0	0	25	0	0
	Licomycin	338	0	0	25	0	0
	Novobiocin	338	0	0	25	0	0
	Virginiamycin	338	0	0	25	0	0
	Sulfathoxypyridazine	134	0	0			
	Sulfachloropyridazine	134	0	0			
	Sulfadimethoxine	134	0	0			
	Sulfamethazine	134	0	0			
	Sulfamethoxypyridazine	134	0	0			
	Sulfathiazole	134	0	0			
	Sulfaquinoxaline	134	0	0			
	Sulfabromomethazine	134	0	0			
	Sulfadiazine	134	0	0			
	Sulfapyridine	134	0	0			
	Arsenic	341	27	0			

YEAR	Monitoring Program				Surveillance Samples		
1988-89	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	300		0			
	Chlorinated OPs	299		0			
	Ivermectin	305		1			
	Penicillin	305		0	552		5
	Streptomycin	305		3	552		1
	Tetracycline	305		0	552		1
	Tylosin	305		0			
	Erythromycin	305		0	552		0
	Neomycin	305		0	552		0
	Oxytetracycline	305		0	552		1
	Chlortetracycline	305		0	552		0
	Gentamicin	305		0	552		0
	Sulfathoxypyridazine	306		0			
	Sulfachloropyridazine	306		0			
	Sulfadimethoxine	306		0			
	Sulfamethazine	306		2			
	Sulfamethoxypyridazine	306		0			
	Sulfathiazole	306		0			
	Sulfaquinoxaline	306		0			
	Sulfabromomethazine	306		0			
	Sulfadiazine	306		0			
	Sulfapyridine	306		0			
	Arsenic	304		1			

YEAR	Monitoring Program				Surveillance Samples		
1990	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	298		0			
	Chlorinated OPs	298		0			
	Ivermectin	310		0			
	Penicillin	313		1	512		14
	Streptomycin	313		17	512		8
	Tetracycline	313		0	512		
	Tylosin	313		0			
	Erythromycin	313		0	512		
	Neomycin	313		0	512		
	Oxytetracycline	313		0	512		
	Chlortetracycline	313		0	512		
	Gentamicin	313		0	512		1
	Sulfathoxypyridazine	313		o			
	Sulfachloropyridazine	313		0			
	Sulfadimethoxine	313		0			
	Sulfamethazine	313		0			
	Sulfamethoxypyridazine	313		0			
	Sulfathiazole	313		0			
	Sulfaquinoxaline	313		0			
	Sulfabromomethazine	313		0			
	Sulfadiazine	313		0			
	Sulfapyridine	313		0			
	Arsenic	310		0			

YEAR	Monitoring Program				Surveillance Samples		
1991	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC screen	106		0			
	Chlorinated OPs	106		0			
	Ivermectin	101		3			
	Penicillin	100		0	708		17
	Streptomycin	100		2	708		17
	Tetracycline	100		0	708		
	Tylosin	100		0			
	Erythromycin	100		0	708		
	Neomycin	100		0	708		
	Oxytetracycline	100		0	708		
	Chlortetracycline	100		0	708		
	Gentamicin	100		0	708		3
	Sulachloropyrazine	106		0			
	Sulfachloropyridazine	106		0			
	Sulfadimethoxine	106		0			
	Sulfamethazine	106		0			
	Sulfamethoxypyridazine	106		0			
	Sulfathiazole	106		0			
	Arsenic	101		0			

YEAR	Monitoring Program				Surveillance Samples		
1992	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	98		1 (coumaphos)			
	Ivermectin	94		2			
	Penicillin	101		0	1008		25
	Streptomycin	101		0	1008		19
	Tetracycline	101		0	1008		0
	Tylosin	101		0			
	Erythromycin	101		0	1008		0
	Neomycin	101		0	1008		0
	Oxytetracycline	101		0	1008		1
	Chlortetracycline	101		0	1008		0
	Gentamicin	101		0	1008		0
	Sulachloropyrazine	103		0			
	Sulfachloropyridazine	103		0			
	Sulfadimethoxine	103		0	1008		1
	Sulfamethazine	103		0	1008		1
	Sulfamethoxypyridazine	103		0			
	Sulfathiazole	103		0			
	Arsenic	94		0			
	Benzimidazoles	99		0			

YEAR	Monitoring Program				Surveillance Samples		
1993	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	425		1 coumaphos 1 dieldrin 1 PCB	Enforcement		11 coumaphos
	Ivermectin	405		0			
	Penicillin	309		2	725		19
	Streptomycin	309		10			8
	Tetracycline	309		0			0
	Tylosin	309		0			0
	Erythromycin	309		0			0
	Neomycin	309		0			0
	Oxytetracycline	309		0			4
	Chlortetracycline	309		0			0
	Gentamicin	309		0			2
	Sulachloropyrazine	306		0			0
	Sulfachloropyridazine	306		0			0
	Sulfadimethoxine	306		1			6
	Sulfamethazine	306		2			0
	Sulfamethoxypyridazine	306		0			0
	Sulfathiazole	306		0			0
	Arsenic	0					

YEAR 1994	Monitoring Program				Surveillance Samples		
	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COP screen	217		0			
	Ivermectin						
	Penicillin	0			421		8
	Streptomycin	0			421		4
	Tetracycline	0					0
	Tylosin	0					0
	Erythromycin	0					0
	Neomycin	0					0
	Oxytetracycline	0					0
	Chlortetracycline	0					0
	Gentamicin	0			421		1
	Sulachloropyrazine	0					
	Sulfachloropyridazine	0					
	Sulfadimethoxine	0					
	Sulfamethazine	0					
	Sulfamethoxypyridazine	0					
	Sulfathiazole	0					
	Arsenic	0					

YEAR 1995	Monitoring Program				Surveillance Samples		
	Compounds	# Analyzed		Violations	# STOP		Violations
	CHC/COPs screen	507		4 coumaphos	Enforcement		
				1 heptachlor	180 samples		0
	Ivermectin						
	Penicillin	0			318		8
	Streptomycin	0					
	Tetracycline	0					
	Tylosin	0					
	Erythromycin	0					
	Neomycin	0					
	Oxytetracycline	0					
	Chlortetracycline	0					
	Gentamicin	0					
	Sulfonamides	0					

YEAR 1996	Program				Surveillance Samples		
	Compounds	Monitoring Analyzed/V	Enforcement Analyzed/V	Violative Compound	# STOP Test/V	# FAST	Violative Componds
	Antibiotics -			**0**	**306/11**		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						**1**
	Penicillin						**8**
	Streptomycin						**2**
	Tetracycline						
	Tylosin						
	Sufonamides -						
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	503/1	53/18	Dieldrin-1			
				Coumaphos-18			
	Trace metals	503	53	none			

Total Horse Slaughter in 1997: 82,025 heads

YEAR	Monitoring Program				Surveillance Samples		
1997	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violations
		Analyzed/V	Analyzed/V	Compounds	Tests/Viol.	Tests/Viol.	Compounds
	Antibiotics -	**386/20**	**0**		**59/1**		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						**1**
	Penicillin			**5**			
	Streptomycin			**17**			
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**234/1**					
	Sulfacloropyridazine						
	Sulfadimethoxine			**1**			
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	457/5		Dieldrin - 1 Heptachlor - 1 PCB - 2 Phenybutazone - 1			
	Arsenic	87/0					
	Ivermectin	256/1					
	Clenbuterol		1,420				

Total Horse Slaughter in 1998: 68,783 heads

YEAR	Monitoring Program				Surveillance Samples		
1998	Compounds	Monitoring	Enforcement	Violative	# STOP	# FAST	Violations
		Analyzed/V	Analyzed/V	Compounds	Tests/Viol.	Tests/Viol.	Compounds
	Antibiotics -	442/20	10-0		70/0		
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			6			
	Streptomycin			15			
	Tetracycline						
	Tylosin						
	Sufonamides -	226/0					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	467/0					
	Arsenic	91/0					
	Ivermectin	292/0					

Total Horse Slaughter in 1999: 64,036 heads

YEAR	Monitoring Program				Surveillance Samples		
1999	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**446**			**222**		
	Bacitracin						
	Chlortetracycline			**2**			
	Erythromycin						
	Flavomycin						
	Gentamicin			**1**			
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline			**1**			
	Penicillin			**8**			**1**
	Streptomycin			**35**			
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**285**					
	Sulfacloropyridazine						
	Sulfadimethoxine			**1**			
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	301		**Phenybutazone**			
				1			

FSIS National Residue Program - Historical Data on Equine Residue Testing

YEAR 2000	Monitoring Program				Surveillance Samples		
	Compounds	**# Analyzed**		**Violations**	**# STOP**	**# FAST**	**Violations**
	Antibiotics -	**434**			**552**		
	Bacitracin						
	Chlortetracycline			**1**			
	Erythromycin						
	Flavomycin						
	Gentamicin			**1**			**1**
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline			**1**			
	Penicillin			**9**			**3**
	Streptomycin			**59**			**2**
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -						
	21 Sulfa compounds			Sulfadimethoxine			
				1			
	CHC/COPs screen	285		**Phenybutazone**			
	21 compound			**1**			
	Avermectin	285		**2**			
	Moxidectin	285					

Total Horse Slaughter in 2003: 50,062 heads

YEAR	Monitoring Program				Surveillance Samples		
2003	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**193**		**0**	**108**	**9**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**199**		**0**			
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**157**		**0**			
	Avermectin	**149**		**0**			
	Moxidectin	**149**		**0**			

Total Horse Slaughter in 2004: 65,200 heads

YEAR	EXPLORATORY Program				Surveillance Samples		
2004	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**15**					
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			**2**			
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**17**					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	15		**Phenybutazone**			
				1			
	Avermectin	**17**					
	Moxidectin						

Total Horse Slaughter in 2005: 93,768 heads

YEAR	EXPLORATORY Program				Surveillance Samples		
2005	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**8**			**85**	**30**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin			**2**			
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**10**					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**9**		**Phenybutazone**			
				1			
	Avermectin	**7**					
	Moxidectin						

Total Horse Slaughter in 2006: 104,433 heads

YEAR	Monitoring Program				Surveillance Samples		
2006	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**112**		**0**	**75**	**4**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -	**0**					
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	281		PBDE - 1			
	Avermectin	**113**		**0**			
	Moxidectin	**113**		**0**			

Total Horse Slaughter in 2007: 29,707 heads

YEAR	Monitoring Program				Surveillance Samples		
2007	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**0**			**7**	**6**	**0**
	Bacitracin						
	Chlortetracycline						
	Erythromycin						
	Flavomycin						
	Gentamicin						
	Hygromycin						
	Neomycin						
	Novobiocin						
	Oxytetracycline						
	Penicillin						
	Streptomycin						
	Tetracycline						
	Tilmicosin						
	Tylosin						
	Sufonamides -						
	Sulfacloropyridazine						
	Sulfadimethoxine						
	Sulfamthazole						
	Sulfadizine						
	CHC/COPs screen	**50**		**0**			
	Avermectin	**54**		**0**			
	Moxidectin	**54**		**0**			

YEAR	Monitoring Program				Surveillance Samples		
2008	Compounds	# Analyzed		Violations	# STOP	# FAST	Violations
	Antibiotics -	**0**			***0***	***0***	
	Sufonamides -	**0**					
	CHC/COPs screen	**0**					
	Avermectin	**0**					
	Moxidectin	**0**					

JUN 2 7 2013

Decision Memo–National Environmental Policy Act Categorical Exclusion

Application of Valley Meat Company, LLC, for a Grant of Federal Meat Inspection Services

Decision

It is my decision to grant federal meat inspection services to Valley Meat Company, LLC.

Description

Valley Meat Company, LLC (Valley Meat) is a small (7,290 square-foot) cattle slaughter and processing facility with a street address of 3845 Cedarvale Rd., Roswell, Chaves County, New Mexico. Valley Meat's zoning permit indicates that its facility is located on a 22-acre site about 12 miles east of Roswell and within an extraterritorial industrial zone that has been set aside in Chaves County for light industrial use. Its nearest neighbors are located approximately one mile to the east and one mile to the west of its facility. Valley Meat has existed as slaughter facility since 1982. Its current owner, Mr. Ricardo de los Santos, has conducted federally inspected commercial slaughter of cattle, veal calves, goats, sheep, lambs, and swine at this facility more or less continuously since January, 1991.[1] On March 2, 2012, Valley Meat filed an application with the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS), to modify its grant of inspection to receive inspection services for the commercial slaughter of horses, mules, and other equines.

Proposed Action

The proposed action is to grant federal meat inspection services for commercial horse slaughter operations at Valley Meat. The Federal Meat Inspection Act (FMIA) requires government inspectors to conduct an ante-mortem inspection of all amenable species, including cattle, sheep, swine, goats, horses, mules and other equines (21 U.S.C. § 603); a post-mortem inspection of the carcasses and parts of all amenable species (21 U.S.C. § 604); and an inspection of meat food products during processing operations (21 U.S.C. § 605) in establishments that sell or distribute in commerce meat that is intended for human consumption. Horses, mules, and other equines have been among the livestock species that are amenable to the FMIA since it was amended by the Wholesome Meat Act in 1967.[2] [3] The FMIA and its implementing regulations in 9 C.F.R.

[1]Valley Meat has operated as a slaughter establishment under several previous grants of federal inspection. It received its first grant in 1982 when it was known as Pecos Valley Meat Company (Pecos) and was under different ownership. Mr. de los Santos took over ownership of Pecos and obtained his first grant of inspection on January 8, 1991. He obtained his second (and still current) grant on September 1, 2010, after adding Mr. Jose Hernandez as a second owner and partner and changing the name of the slaughter plant to Valley Meat. Valley Meat has not operated under its current grant since April 13, 2012.

[2]FSIS regulations require that establishments that slaughter horses, mules, and other equines must be completely separate from any establishment that slaughters cattle, sheep, swine, or goats.

[3]FSIS temporarily suspended inspection of horse slaughter facilities from 2006 to 2012 because Congress prohibited FSIS from expending funds to pay for ante-mortem inspection of equines in each of those years, but the underlying statute requiring federal inspection of horse slaughter has never been amended or repealed. In 2012 Congress restored federal funding of ante-mortem inspection of horses at commercial horse slaughter plants. Therefore, issuing a grant of inspection for commercial horse slaughter is not precedent setting, but rather, a return to the status quo ante.

If NMED renews Valley Meat's DP-236, most of the water used by Valley Meat will become wastewater that ultimately will be discharged into the establishment's treatment and disposal system. Some of the blood produced by its slaughter operations likewise will drain into the establishment's treatment and disposal system.[6] Valley Meat uses a septic tank and lagoons to treat and dispose of its wastewater and effluent. The soil conditions found in and around Chavez County are conducive to the use of septic systems because the soil is moderately permeable, which allows for effluent absorption without over-saturation. The soil also has thick, impermeable layers of clay that protect the area's shallow aquifers. Therefore, the wastewater used in and blood generated by Valley Meat's commercial horse slaughter operations should not impact the local ground and surface water.

Conclusion.

Based on the foregoing, FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant federal meat inspection services to Valley Meat that would cause this action to have a significant environmental effect. Therefore, in accordance with 7 C.F.R. § 1b.4, the proposed action is categorically excluded from the preparation of an EA or an EIS.

[6]Some opponents of commercial horse slaughter have claimed that horses have, pound-for-pound, twice as much blood volume as cows, and that the blood produced by commercial horse slaughter will overwhelm any waste water disposal system. According to FSIS veterinarians, the blood volume of the average horse ranges from 6.14% to 8.63% of live animal weight, as opposed to 6.75% of live animal weight for the average cow, and thus is not appreciably different from that of cows. Furthermore, the volume of horse blood that commercial horse slaughter at Valley Meat is likely to produce will be a function of the sizes and breeds of the horses that are slaughtered there and the volume of horse slaughter and thus is highly speculative. As noted above, Valley Meat is located 12 miles from the nearest municipality and relies on septic tanks and lagoons for waste water disposal, rather than Roswell's waste water disposal system. Given the speculative nature of the horse slaughter opponents' claims about horse blood volumes, Valley Meat's distance from Roswell, and the nature of Valley Meat's waste water and disposal system, there is no reason to believe that Valley Meat's waste water and disposal system is inadequate to handle the volume of horse blood that is likely to be produced by commercial horse slaughter operations at its facility.

commercial horse slaughter have indicated their intention to challenge any grant of federal inspection for commercial horse slaughter at Valley Meat on ESA grounds, , FSIS has engaged in informal consultation with FWS concerning the potential effects of commercial horse slaughter on endangered or threatened species and their critical habitat.6

On May 6, 2013, FSIS consulted the Aquatics Branch of FWS's Ecological Services Field Office in New Mexico to discuss whether commercial horse slaughter activities at Valley Meat or federal inspection thereof will have any impact, either directly or indirectly, on any federally or state-listed or proposed endangered species of flora and fauna or impact a critical habitat. Specifically, they discussed the species and critical habitats listed on FWS's Web site at http://www.fws.gov/southwest/es/newmexico/sbc_view_all_bc.cfm.

FSIS provided FWS with a map of Mr. de los Santos' property[7] that indicated that his facility is located at 33° 21' N/ 104° 25' W. FSIS then described to FWS the activities that the Agency will conduct at this facility. Specifically, FSIS will provide inspection program personnel to the facility to examine horses before and after slaughter. FSIS will verify requirements for marking and labeling products and for certain slaughter and processing activities, such as plant sanitation. Furthermore, FSIS will collect samples and test for microbiological, chemical, and other types of contamination.

FSIS also described to FWS how Mr. de los Santos will slaughter horses at his facility. Horses will be sent to the facility in trucks. Mr. de los Santos will store the horses in holding pens until the horses can be brought into the facility for slaughter. Mr. de los Santos will not use any chemicals or sprays on the live horses. After slaughter, Mr. de los Santos will spray carcasses with [redacted] to limit microbial growth.

Valley Meat will use bleach and [redacted] (quaternary ammonium) from [redacted] to clean and sanitize the facility. The establishment will also use some insecticide to control flies around the facility.

The facility will use a septic system and lagoons to manage its liquid waste. The septic system will receive the raw sewage and other effluent from the establishment. In the septic tank, solids will be separated out of the raw sewage and partially digested by anaerobic bacteria. After primary treatment in the septic tank, liquid effluent will flow to the lagoons through a watertight pipe and discharge near the center of the bottom of the lagoons. There the wastewater will be further processed by aerobic bacteria. Neither the FMIA nor the grant of federal inspection for which Valley Meat is applying authorizes or mandates any of the foregoing. Rather, Valley Meat's management of its liquid waste is governed solely by federal and state clean water laws. Pursuant to the latter, the facility currently is applying for a renewal of its DP-236, a discharge permit from the State of New Mexico, for the discharge of up to 8,000 gallons of agricultural wastewater per day.

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6 Consultation number 02ENNM00-2013-TA-0048.
7 Attachment 1.

Solid wastes will be stored at the establishment in an inedible area inside a freezer until the waste can be picked-up by a rendering company for disposal. The waste will be collected approximately three times per week.

FWS advised FSIS that there is no undisturbed native habitat and, therefore, no suitable habitat in or near Valley Meat's facility. FWS also did not believe that the establishment's use of chemicals to limit microbial growth and to clean and sanitize the facility would affect any listed species or their designated critical habitats because the establishment previously used these compounds with no discernible effects on listed species or their habitats.

FWS advised FSIS that that the establishment's liquid and solid waste management system will not affect listed species or their critical habitats. Valley Meat's septic and lagoon system treats the facility's wastewater so that it is safe to use for irrigation on the land near the slaughter facility and will not contaminate the area's groundwater. In addition, sending the solid waste to an off-site rendering facility prevents any spillage that could impinge on a listed species' habitat. Furthermore, the listed species and critical habitats exist upstream from the facility so they would not be affected even if the groundwater was contaminated or solid waste was spilled.

FSIS has determined that there will be "no effect" on listed species or designated critical habitats because of commercial horse slaughter activities or federal inspection thereof and FWS concurs. Tables 1 and 2 summarize the potential listed species found on FWS's Web site, the effect determination, and the rationale for the determination.

Table 1: Listed and Sensitive Species in Chaves County

Common Name	Scientific Name	Group	Status	Determination	Rationale
Lesser prairie-chicken	*Tympanuchus pallidicinctus*	Bird	Candidate	No Effect	No Suitable Habitat
Sprague's pipit	*Anthus spragueii*	Bird	Candidate	No Effect	No Suitable Habitat
Texas hornshell (mussel)	*Popenaias popeii*	Mollusc - Invertebrate	Candidate	No Effect	No Suitable Habitat
Wright's marsh thistle	*Cirsium wrightii*	Plant	Candidate	No Effect	No Suitable Habitat

NMED Discharge Permit Renewal Application Part B General

Part B-6

Pecos Valley Meat DP-236

Operational Plan

Facility Operating System

The processing facility operating system is comprised of the following components: [redacted]

Facility Operations

The operation of these system components is briefly described as follows:

[redacted]

[redacted]

JUL 0 1 2013

Decision Memo—National Environmental Policy Act Categorical Exclusion

Application of Responsible Transportation, LLC, for a Grant of Federal Meat Inspection Services

Decision

It is my decision to grant federal meat inspection services to Responsible Transportation, LLC.

Description

Responsible Transportation, LLC (Responsible Transportation), is a 34,600 sq ft brick-walled masonry building that is located on an 80.64-acre site at 22034 200th Street, Sigourney, Keokuk County, Iowa. The facility, built in 1977, was previously used by West Liberty Foods, LLC, for processing beef products. The facility is one-half mile from the nearest occupied house. Responsible Transportation filed an application for a Grant of Inspection on December 13, 2012. Mr. Keaton Walker is President of Responsible Transportation.

Proposed Action

The proposed action is to grant federal meat inspection services for commercial horse slaughter operations at Responsible Transportation. The Federal Meat Inspection Act (FMIA) requires government inspectors to conduct an ante-mortem inspection of all amenable species, including cattle, sheep, swine, goats, horses, mules and other equines (21 U.S.C. § 603); a post-mortem inspection of the carcasses and parts of all amenable species (21 U.S.C. § 604); and an inspection of meat food products during processing operations (21 U.S.C. § 605) in establishments that sell or distribute in commerce meat that is intended for human consumption. Horses, mules, and other equines have been among the livestock species that are amenable to the FMIA since it was amended by the Wholesome Meat Act in 1967.[1] [2] The FMIA and its implementing regulations in 9 CFR parts 302, 304, 307, 416, and 417 require establishments that wish to engage in the commercial slaughter of amenable species to produce meat intended for human consumption and sale or distribution in interstate commerce to apply to FSIS for a grant of federal inspection services, and they establish criteria for determining the eligibility of the applicant to receive inspection services.

FSIS is also required to conduct an examination and inspection of the method by which amenable species, including horses, are slaughtered and handled in connection with slaughter in order to ensure that the establishment is in compliance with the Humane Methods of Slaughter Act (21

[1]FSIS regulations require that establishments that slaughter horses, mules, and other equines must be completely separate from any establishment that slaughters cattle, sheep, swine, or goats.

[2]FSIS temporarily suspended inspection of horse slaughter facilities from 2006 to 2012 because Congress prohibited FSIS from expending funds to pay for ante-mortem inspection of equines in each of those years, but the underlying statute requiring federal inspection of horse slaughter has never been amended or repealed. In 2012 Congress restored federal funding of ante-mortem inspection of horses at commercial horse slaughter plants. Therefore, issuing a grant of inspection for commercial horse slaughter is not precedent setting, but rather, a return to the status quo ante.

--**Migratory Bird Treaty Act.** FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not affect species protected under the Migratory Bird Treaty Act.

--**National Historic Preservation Act.** The National Register of Historic Places lists 12 sites located in the Sigourney, IA, area. According to information from the State Historical Society of Iowa and the National Register of Historic Places the property owned by Responsible Transportation is not on the list of historic places in Keokuk Country, IA, and the listed historic site closest to Responsible Transportation, the Sigourney Public Library, is over two miles away from the slaughter facility. Therefore, FSIS has determined that commercial horse slaughter activities at Responsible Transportation or federal inspection thereof will not impact any historic or cultural property or resources protected by the National Historic Preservation Act.

In 2009, a coalition of northwest Indian tribes reported to the GAO that the increase in horse abandonments on tribal lands, combined with the sizable populations of wild horses that already existed on their lands, both increased the degradation of the land caused by over-grazing and complicated efforts to restore native and religiously-significant plant species on tribal lands. Commercial horse slaughter at Responsible Transportation and other commercial horse slaughter plants thus has the potential to have a beneficial effect on the cultural resources of American Indian tribes whose tribal lands are being degraded by a combination of an overpopulation of wild horses and large scale abandonment of unwanted horses on their lands.

--**Federal Farmland Protection Policy Act.** FSIS has determined that federal inspection of the slaughter activities at Responsible Transportation will not involve the acquisition or use of farmland protected by the Federal Farmland Protection Policy Act that would be converted to non-agricultural use.

–**Humane Methods of Slaughter Act.** As previously noted, Responsible Transportation's commercial horse slaughter operations will be subject to the humane handling requirements found in section 603(b) of the FMIA (21 U.S.C. § 603(b)) and the regulations promulgated thereunder (9 CFR part 313).

--**State and Local Laws.** As previously noted, Responsible Transportation's facility is located in the City of Sigourney, Keokuk County, IA.

Under the terms of a water supply operation permit issued February 25, 2013, by the Iowa Department of Natural Resources (IDNR), Responsible Transportation is authorized to operate a public water system under the applicable sections of the Iowa Code, including Chapter 455B and part 567 of the Iowa Administrative Code. The system is subject to monitoring requirements and general conditions detailed in the permit.

Under the conditions of a water use permit that originally was issued to West Liberty Foods, effective on September 20, 2001, and renewed on April 16, 2013, by IDNR, Responsible Transportation is authorized to withdraw water from three existing wells, ranging from 103 to 123 feet deep, that are located on land in the Northwest quarter of Section 30, T76N, R11W, Keokuk

County, IA. The water use permit allows Responsible Transportation to withdraw a maximum quantity of 18.25 million gallons per year at a maximum rate of 55 gallons per minute throughout each year for use in the operation of a meat processing plant.

Responsible Transportation's waste disposal system operates in accordance with an IDNR permit for a land application system that was issued March 1, 2013, pursuant to the authority of Iowa Code section 455B.174 and rule 567-64.3 of the Iowa Administrative Code.

Wastewater from Responsible Transportation's processing facility is treated in a lagoon system consisting of anaerobic lagoon and two aerobic storage lagoon cells. The treated wastewater is disposed of by land application using a center-pivot irrigation system. The 40-acre land application area is in the Northwest quarter of Section 30, T76N, R11W, Keokuk County, IA. A key condition of the permit is that no discharge into the waters of the State from the storage lagoon or the land application area is allowed. Other conditions are listed in the permit document.

Conclusion.

Based on the foregoing, FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant federal meat inspection services to Responsible Transportation that would cause this action to have a significant environmental effect. Therefore, in accordance with 7 CFR § 1b.4, the proposed action is categorically excluded from the preparation of an EA or an EIS.

In 2009, a coalition of northwest Indian tribes reported to the GAO that the increase in horse abandonments on tribal lands, combined with the sizable populations of wild horses that already existed on their lands, both increased the degradation of the land caused by over-grazing and complicated efforts to restore native and religiously-significant plant species on tribal lands. Commercial horse slaughter at Rains Natural Meats and other commercial horse slaughter plants thus has the potential to have a beneficial effect on the cultural resources of American Indian tribes whose tribal lands are being degraded by a combination of an overpopulation of wild horses and large scale abandonment of unwanted horses on their lands.

--**Federal Farmland Protection Policy Act**. FSIS has determined that federal inspection of the slaughter activities at Rains Natural Meats will not involve the acquisition or use of farmland protected by the Federal Farmland Protection Policy Act that would be converted to non-agricultural use.

–**Humane Methods of Slaughter Act**. As previously noted, Rains Natural Meats' commercial horse slaughter operations will be subject to the humane handling requirements found in section 603(b) of the FMIA (21 U.S.C. § 603(b)) and the regulations promulgated thereunder (9 C.F.R. Part 313). FSIS never suspended Rains Natural Meats for humane handling violations during its previous commercial slaughter of other amenable species.

--**State and Local Laws**.

Rains Natural Meats' waste disposal is governed by Missouri's Solid Waste Management Law ("SWML") (Mo. Rev. Stat. 260.005 *et seq.*). It is a violation of the SWML to store, process, or dispose of solid waste in an unapproved manner and to dispose of any solid waste in a place other than an approved solid waste processing facility (Mo. Rev. Stat. 260.210. 1). Pursuant to the SWML, Rains Natural Meats will collect all blood and organs after stunning and evisceration and store the materials in barrels. Darling International, Inc., a rendering company, will regularly collect the barrels and deliver them to its rendering facility in Des Moines, Iowa, where they will be rendered according to local, state, federal laws.

Rains Natural Meats' disposal of wastewater is governed by Missouri's Clean Water Law (Mo. Rev. Stat. 640.006 *et seq.*). In accordance with the Clean Water Law, Rains Natural Meats will discharge its wastewater into the City of Gallatin's wastewater collection system which consists of over 191 miles of sanitary sewer lines and 22 sanitary sewer pumping stations. [14] This system will transport water from Rains Natural Meats to the Gallatin Wastewater Treatment Plant for processing and eventual discharge of a high quality effluent back into Old Hickory Lake. The wastewater treatment plant has an organic treatment capacity of 12.5 million gallons per day. The plant is also capable of being operated in "Storm Mode" with a resulting hydraulic capacity in excess of 30 million gallons per day, while meeting all National Pollutant Discharge Elimination System effluent limitations set by the EPA.[15]

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14 http://www.gallatinutilities.com/wastewater.html.

15 http://www.gallatinutilities.com/wwtp.html.

Conclusion.

Based on the foregoing, FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant federal meat inspection services to Rains Natural Meats that would cause this action to have a significant environmental effect. Therefore, in accordance with 7 C.F.R. § 1b.4, the proposed action is categorically excluded from the preparation of an EA or an EIS.

9/13/13

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