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-MCA-RHS

FEDERAL DEFENDANTS' RESPONSE BRIEF ON THE MERITS[1]

[1] This Response Brief is filed in accordance with the Court's September 26, 2013 Order, which provides that the length of the parties' response briefs will be up to 17,500 words. ECF No. 179. Undersigned counsel for Federal Defendants hereby certifies that this Response Brief contains 17,156 words.

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RELATED CASES

This case is related to another case pending in the District of New Mexico,

Valley Meat Company, LLC, v. Tom Vilsack, Secretary, U.S. Department of Agriculture, et al., Civil No. 2:12-cv-01083-JCH-CG. Federal Defendants' July 12, 2013 "Notice of Related Cases and Motion to Transfer," ECF No. 39, is fully briefed and pending.

TABLE OF AUTHORITIES

FEDERAL CASES

ISSUES ON APPEAL

1. Do the requirements of the National Environmental Policy Act ("NEPA"), 42 U.S.C. §§4321-4370h, apply to the nondiscretionary duty of the U.S. Department of Agriculture ("USDA") Food Safety Inspection Service ("FSIS") to grant inspections at slaughter facilities meeting the requirements of the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. §§601-625?

2. Even NEPA applies to grants of inspection under FMIA, was FSIS's invocation of its categorical exclusion ("CE") pursuant to NEPA arbitrary and capricious and inconsistent with the agency's regulation, 7 C.F.R. §1b.4?

3. Is Directive 6130.1, FSIS's internal instructions to its agency employees, "final agency action" subject to judicial review under the Administrative Procedure Act ("APA"), 5 U.S.C. §704, and, even if it is, is it subject to the procedural requirements of NEPA?

4. Are Plaintiffs entitled to relief?

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY FRAMEWORK

A. The National Environmental Policy Act

NEPA requires federal agencies proposing "major Federal actions significantly affecting the quality of the human environment" to prepare an environmental impact statement ("EIS"). 42 U.S.C. §4332(2)(C). The purpose of

NEPA is to ensure that agencies take a "hard look" at potential environmental consequences before approving any major federal action. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 350 (1989). NEPA, however, is an "essentially procedural" statute and does not require an agency to follow the most environmentally sound course of action. *Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 558 (1978); *Robertson*, 490 U.S. at 350. "NEPA does not work by mandating that agencies achieve particular substantive environmental results." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 371 (1989).

Regulations promulgated by the Council on Environmental Quality ("CEQ"), 40 C.F.R. §§1500-18.4, allow an agency to comply with NEPA in three ways. First, the agency may always prepare an EIS. 40 C.F.R. §1501.3. An EIS is a detailed statement subject to extensive regulations regarding format, content, and methodology. 40 C.F.R. Part 1502. Second, the agency may prepare an environmental assessment ("EA"), *see id.* §§1501.4(b), 1508.9, and based on the EA either determine that an EIS is necessary or issue a finding of no significant impact ("FONSI"). *See id.* §§1501.4(e), 1508.13. An EA is a "concise public document" that "[b]riefly provide[s] sufficient evidence and analysis for determining whether" the action will have a "significant" effect on the environment, the threshold for preparation of an EIS. 40 C.F.R. §1508.9. Third, the agency need not prepare an EA or an EIS, if the agency determines that the

proposed action falls within an established "categorical exclusion" or "CE." *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) (describing NEPA requirements).

CEs are "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. In other words, if an agency determines that a particular category of action will not have a significant effect on the environment, the agency may establish a CE and need not prepare an EA or EIS when conducting a future action that falls within in the category. The only exception is that an agency must make allowances for "extraordinary circumstances in which [the] normally excluded action may have a significant environmental effect." *Id.*; *California v. Norton*, 311 F.3d 1162, 1177 (9th Cir. 2002); *Citizens' Comm. to Save Our Canyons v. U.S. Forest Serv.*, 297 F.3d 1012, 1023 (10th Cir. 2002).

CEs are an integral part of the framework for demonstrating compliance with NEPA and are, in fact, required by CEQ's regulations. *See* 40 C.F.R. §1507.3(b)(2)(ii). The use of CEs allows agencies to focus their environmental review efforts on major actions that will have significant effects on the environment and which are the primary focus of NEPA. 48 Fed. Reg. 34,263-01, 34,263-66 (July 28, 1983); *see also* 40 C.F.R. §1500.4(p) (noting that

establishment and use of CEs can reduce excessive paperwork by eliminating unnecessary preparation of EAs). CEQ thus has encouraged agencies to identify CEs using "broadly defined criteria which characterize types of actions that, based on the agency's experience," normally do not have "significant environmental effects." 48 Fed. Reg. at 34,265.

B. Federal Meat Inspection Act

Congress enacted FMIA 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). As amended and codified, "FMIA regulates a broad range of activities at slaughterhouses to ensure both the safety of meat and the humane handling of animals." *Id*. In its current version, FMIA applies to certain "amenable species," including "cattle, sheep, swine, goats, horses, mules, and other equines." 21 U.S.C. §601(w) (incorporating Wholesome Meat Act, Pub. L. No. 90-201, §12(a), 81 Stat. 592 (1967)).

FMIA requires that 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." *Id*. §603(a). FMIA 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. FMIA prohibits the sale or transport "in commerce" of any article involving "any cattle, sheep, swine, goats, horses, mules, or other equines, 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 FMIA. *Id*. §610(c).

Inspections under FMIA must be conducted by "inspectors appointed for that purpose." 21 U.S.C. §§603(a), 604. FSIS, as the delegate of USDA, 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 [FMIA]" must "make application" to FSIS before "inspection is granted." 9 C.F.R. §304.1(a). "[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." *Id.* at §304.2(b).

A successful applicant receives a conditional grant of inspection for ninety days to validate a plan for managing food safety, known as a Hazard Analysis and Critical Control Point ("HACCP") plan. 9 C.F.R. §304.3(b). A HACCP plan is part of "a management system in which food safety is addressed through the analysis and control of biological, chemical and physical hazards." 9 C.F.R.

§304.3(b). An establishment validates its HACCP plan by conducting certain activities "designed to determine that the HACCP plan is functioning as intended." 9 C.F.R. §417.4(a)(1).

II. STATEMENT OF FACTS

A. The Grants Of Inspection

Valley Meat Company is a small cattle slaughter and processing facility in Roswell, New Mexico. AR0002467. Its current owner, Ricardo de los Santos, has conducted federally-inspected commercial slaughter of cattle, veal calves, goats, sheep, lambs, and swine at the facility since approximately 1991. *Id*. On June 28, 2013, FSIS approved Valley Meat's application consistent with a CE promulgated pursuant to NEPA. AR0002467.

Responsible Transportation, LLC, is a facility located in Sigourney, Iowa. AR0003282. The facility was previously used by West Liberty Foods for processing beef products, but is currently closed. *Id*. On December 13, 2012, Responsible Transportation filed an application with FSIS to grant federal meat inspection services for commercial horse slaughter operations to produce food for human consumption. *Id*. On July 2, 2013, FSIS approved Responsible Transportation's application consistent with a CE issued pursuant to NEPA. *Id*.

Rains Natural Meats in Gallatin, Missouri, submitted an application on January 15, 2013. AR0004868. On September 13, 2013, FSIS issued a CE issued

pursuant to NEPA as to Rains Natural Meat's application for federal inspection. AR0004868-78.

B. Directive 6130.1

On June 28, 2013, FSIS issued Directive 6130.1. AR00001861. The Directive 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." AR00001861. 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." AR00001861. The Directive provides for FSIS inspectors to conduct intensified random drug residue testing of healthy-appearing equines. AR0001866-67. *See also* Declaration of Dr. Daniel L. Engeljohn, Ph.D. ("Engeljohn Decl."), ECF No. 66-1 ¶16. 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. *Id.* ¶¶8-10; 14-16. This multi-residue method of testing tissues detects up to 52 analytes. *Id*. ¶15. The drug residues tested include those of potential public health concern for all livestock, including equines. *Id.*

C. The Multi-Agency Drug Residue Testing Program

Under FMIA, meat or meat food products are adulterated if they bear or contain a pesticide chemical which is unsafe within the meaning of the Federal Food Drug and Cosmetic Act ("FFDCA"). 21 U.S.C. §601(m)(2)(B). Under the FFDCA, the Food and Drug Administration ("FDA") has the statutory authority to establish residue tolerances for veterinary drugs, food additives, and environmental contaminants. *Id*. The Environmental Protection Agency ("EPA"), under the Federal Insecticide, Fungicide and Rodenticide Act, establishes tolerance levels for registered pesticides. 7 U.S.C. §§ 136-136y.

FSIS administers the United States National Residue Program ("NRP"), which is designed to protect the public from exposure to levels of chemical or pesticide residues in meat and meat food products that exceed tolerances or action levels set by FDA or EPA. 77 Fed. Reg. 39,895 (July 6, 2012); Engeljohn Decl. ¶10. The NRP requires the cooperation and collaboration of several agencies for successful design and implementation, including FSIS, EPA, and FDA. 77 Fed. Reg. 39,895; Engeljohn Decl. ¶12. The NRP is designed to provide a structured process for identifying and evaluating chemical compounds of concern in food animals; collecting, analyzing and reporting results; and identifying the need for regulatory follow-up when violative levels of chemical residues are found. *Id*. at ¶¶10-11. The NRP tests for the presence of chemical compounds, including

approved (legal) and unapproved (illegal) veterinary drugs, pesticides, hormones, and environmental contaminants that may appear in meat, poultry, and egg products. *Id*.

A scheduled residue sampling program is developed annually by representatives from FSIS, FDA, EPA, and other Federal agencies, including the USDA Agricultural Research Service, the Agricultural Marketing Service, and the Centers for Disease Control and Prevention. 77 Fed. Reg. 39,895-96; Engeljohn Decl. ¶12. These agencies meet at least once a year as part of the Surveillance Advisory Team. This Team creates the annual sampling plan using sample results from the NRP, information that agencies have accumulated during investigations, and information from veterinary drug inventories that FDA has compiled during on-farm visits. The agencies create a list of chemical compounds for testing and rank them using mathematical equations that include variables for public health risk and regulatory concern. In addition to establishing a relative ranking for the chemicals, the Team determines the compound/production class pairs of public health concern and evaluates FSIS laboratory capacity and analytical methods to devise a final sampling plan. FSIS publishes the final sampling plan in the NRP Sampling Plan.

Since 1967, FSIS has administered the NRP by collecting samples from meat, poultry, and egg products and analyzing the samples at one of three FSIS

laboratories. In practice, the NRP consists of three separate but interrelated chemical residue testing programs: scheduled sampling, inspector-generated sampling, and import sampling. This basic structure has been modified over time to adjust to emerging and reemerging chemical residue concerns and to improvements in testing methodologies. When an FSIS laboratory detects a chemical compound level in excess of an established tolerance or action level in a sample, then a basis for concern exists. FSIS shares laboratory findings that exceed established tolerances and action levels with FDA or EPA. FDA has jurisdiction on-farm, and FSIS assists FDA in obtaining the names of producers and other parties involved in offering the animals for sale. FSIS informs producers through certified letters when an animal from their business has a violative level of a residue. FDA and cooperating State agencies investigate producers linked to residue violations. If a problem is not corrected, subsequent FDA visits could result in an enforcement action, including prosecution. 77 Fed. Reg. 39,895.

In July 2012, FSIS announced that it was restructuring the NRP with respect to how sampling of chemical compounds and animal production and egg product classes is scheduled. 77 Fed. Reg. 39,895; Engeljohn Decl. ¶13. To complement this new approach to sampling and scheduling, FSIS implemented several multi-residue methods for analyzing samples of meat, poultry, and egg products for animal drug residues, pesticides, and environmental contaminants in its inspector-

generated testing program. These modern, high-efficiency methods will conserve resources and provide useful and reliable results while enabling FSIS to analyze each sample for more chemical compounds than was previously possible. Under the new program, FSIS will collect fewer samples, but analyze the samples for a greater number of chemical compounds. This multi-residue method has already provided significant improvements to the NRP because it can: (a) screen for a variety of analytes, not just antibiotics; (b) be validated at levels appropriate in relation to tolerances; can clearly distinguish individual analytes even if multiple drugs are present in the sample (due to the power of mass spectrometry); (c) mitigate unknown microbial inhibition responses; and (d) reduce the time and personnel needed to obtain results. 77 Fed. Reg. 39,897; Engeljohn Decl. ¶¶13-14. The new methods were validated for use in cattle and swine. *Id*. ¶14.

When FSIS received applications for grants of inspection for horse slaughter, it reviewed the residue testing data that was collected from 1983 through 2007, *and concluded the compounds likely to be used in equines mirror to a large extent those for other amenable species*. AR0001825 (emphasis added). Accordingly, FSIS validated the methods that it uses to test other amenable species for use on equine meat. *Id*. *See also* 77 Fed. Reg. 39,895; AR0003923 (Vilsack letter to Congress); AR0003928 (FSIS letter to HSUS).

D. The Inspections

FSIS inspectors conduct an ante-mortem inspection of all live horses on the day of slaughter. The inspectors observe the horses at rest and in motion in order to determine whether they are fit for slaughter for human consumption. Inspectors look for indications of illegal drug use and will designate animals for drug residue testing if they observe injection sites or health conditions that would require treatment with drugs, such as pneumonia, pleuritis, septicemia, signs of recent surgery, injury, or inflammatory conditions. AR0000964-65; AR0001866-67. Animals exhibiting these symptoms are designated as "U.S. Suspect" and are required to be segregated from other horses and slaughtered separately from other livestock at the establishment. 9 C.F.R. §309.2(n). After slaughter, an FSIS inspector will retain the carcass and parts and submit the appropriate tissue sample for further testing at an FSIS laboratory. AR0001866. If the laboratory test detects any drug residues, the carcass and parts are condemned and destroyed for human food purposes. AR0000967; AR0001867-68. *See also* 21 U.S.C. §606(a).

Additionally, after slaughter, FSIS inspectors conduct random residue testing of normal-appearing horses to provide additional assurance that carcasses are free from drug residues. AR0001866-67. This random testing is conducted at the same or a higher rate as that used for show livestock, such as steers, heifers, market hogs, sheep and lambs. AR0001867; AR0002021; Engeljohn Decl. ¶ 16.

For establishments that have a good compliance history, the minimum frequency of testing will be four to ten percent of the healthy-appearing horses slaughtered during a slaughter shift. Engeljohn ¶16. If, however, samples from a given establishment test positive for drug residues, FSIS inspectors may increase the rates of sampling and testing up to one hundred percent, if necessary. AR0002023; Engeljohn ¶16.

SUMMARY OF ARGUMENT

Plaintiffs cannot succeed on the merits of their NEPA claims.[1] FMIA *mandates* that FSIS grant inspections of livestock slaughter at facilities such as Valley Meat, Responsible Transportation, and Rains Natural Meats that meet the requirements of FMIA. FMIA does not afford FSIS discretion to deny or condition a grant of inspection for a qualifying facility on environmental grounds. Nor does FMIA give FSIS authority or control over any environmental impacts that may

[1] Plaintiffs' alleged environmental injuries will only occur vis a vis the actions of a third party if 1) the slaughter facilities present horses for slaughter that contain impermissible drug residues that will escape FSIS's testing procedures on at a large scale and 2) the facilities violate the federal, State, and local laws governing their discharges and disposal activities. *Clapper v. Amnesty Int'l USA*, 133 S.Ct. 1138, 1151 (2013) (plaintiffs "cannot manufacture standing merely by inflicting harm on themselves based on their fears of hypothetical future harm."); *Los Angeles v. Lyons*, 461 U.S. 95, 107 n.8 (1983) (plaintiff's "subjective apprehensions" that allegedly unlawful conduct would occur again were not enough to support Article III standing); *Ctr. for Food Safety v. Vilsack*, 636 F.3d 1166, 1171 n.6 (9th Cir. 2011) ("Of course, as our decision illustrates, a plaintiff may establish standing to seek injunctive relief yet fail to show the likelihood of irreparable harm necessary to obtain it.").

flow from operations at a qualifying facility. Because FSIS lacks such discretion, environmental review pursuant to NEPA cannot meaningfully inform or change its decision to grant or deny an inspection.

The outcome of this case is dictated by the Supreme Court's decision in *National Association of Home Builders ("NAHB") v. Defenders of Wildlife*, 551 U.S. 644 (2007). In *NAHB*, the Supreme Court held that the environmental considerations required by the ESA--which the Court analogized to NEPA, even while noting that the ESA contains more rigid requirements than NEPA, *id.* at 667-68--apply to only discretionary agency actions. *Id.* at 673. Thus, the Supreme Court held that because the Clean Water Act provides that the EPA "shall" grant a State permitting authority under the Act unless the EPA determines that the State does not meet the requirements of the Act, *id.* at 661, the grant of permitting authority is not discretionary and does not trigger the ESA consultation requirements. *Id.* at 673. In accordance with *NAHB*, because FMIA dictates that FSIS "shall" grant inspections to facilities unless FSIS determines that the facility does not meet the requirements of FMIA, 21 U.S.C. §§603, 604, FSIS's grant of permitting authority is not discretionary and does not trigger NEPA obligations. Therefore, Plaintiffs' NEPA claims must be denied.

Even if NEPA applied to FSIS's grants of inspections, FSIS satisfied NEPA by properly invoking a CE for its actions. USDA's applicable NEPA regulation

categorically excludes *all* FSIS activities from preparation of an EA or EIS, unless FSIS determines that extraordinary circumstances exist such that an action "may have a significant environmental effect." 7 C.F.R. § 1b.4. Plaintiffs seek to have this Court judicially amend this regulation to render it inapplicable to all grants of inspection for even small operations such as those at issue here, solely because those operations involve the slaughter of horses. Plaintiffs' postulated *per se* "extraordinary circumstance" for all horse slaughter operations is based on their assertion that "virtually every American horse" presented for slaughter will contain the residues of drugs not intended for use in animals intended for human consumption, and that slaughter will cause these drugs to "contaminat[e] local ecosystems and water and soil supplies." Pls.' Br., ECF No. 170 at 36-37.

But the *only* experts before the Court--experts entitled to special deference pursuant to the APA--have examined and rejected Plaintiffs' assertion that horses presented for slaughter will contain harmful drug residues. After careful consideration, the experts at FSIS found "no merit," AR0001853, and "no basis in the statute or in science" to support Plaintiffs' assertion because "[a]fter 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." AR0001854. And, even if an animal contained harmful drug residues at the time of slaughter, FSIS's drug residue testing program would be "effective in preventing adulterated

horsemeat from entering the human food supply." AR0001855. As the Supreme Court has repeatedly emphasized, in deciding disputes that involve primarily issues of fact that "'require[] a high level of technical expertise,' [the court] must defer to 'the informed discretion of the responsible federal agencies.'" *Marsh*, 490 U.S. at 377 (quoting *Kleppe v. Sierra Club*, 427 U.S. 390, 412 (1976)).

Because horse slaughter operations do not pose the unique concerns to the environment from drug residue to the degree Plaintiffs erroneously claim, FSIS reasonably determined that its grants of inspection for Valley Meat, Responsible Transportation, and Rains Natural Meats would fall under the "CE" for actions that USDA has found have no significant impacts on the environment. Therefore, even if the Court were to find that NEPA applied to FSIS's grants of inspection, Plaintiffs' NEPA claims would still fail because FSIS has complied with NEPA by properly determining the grants of inspection fall within an existing CE.

Plaintiffs' challenge to Directive 6130.1 is likewise without merit. In the first instance, the Directive does not constitute a "final agency action" subject to judicial review under the APA, 5 U.S.C. § 704. The instructions in the Directive do not establish any legal rights or obligations, particularly Plaintiffs', because they do not apply to anyone other than the FSIS's employees. AR0004870-71. Thus, the Directive does not meet either of the test for "final agency action" set

forth in *Bennett v. Spear*, 520 U.S. 154 177-78 (1997). Plaintiffs' challenge to the Directive is not cognizable and therefore must be dismissed.

Even if the Directive were subject to judicial review, its adoption does not trigger any NEPA obligations. NEPA applies only when "an agency action constitutes an 'irreversible and irretrievable commitment of resources,' which exists only where the government surrenders its 'absolute right' to prevent the use of those resources." *Friends of Se.'s Future v. Morrison*, 153 F.3d 1059, 1064 (9th Cir. 1998) (quoting *Conner v. Burford*, 848 F.2d 1441, 1449 (9th Cir. 1988)). As non-binding internal agency guidance that can be canceled or modified at any time, the Directive makes no commitment of resources to any particular action, and the Directive does not surrender any right of FSIS to deny an application for a grant of inspection if an applicant fails to meet the qualifications for inspection.

Moreover, to trigger a NEPA obligation, "NEPA requires 'a reasonably close causal relationship' between the environmental effect and the alleged cause." *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 767 (2004) (quoting *Metro. Edison Co. v. People Against Nuclear Energy*, 460 U.S. 766, 774 (1983)). The environmental effects alleged by Plaintiffs are caused by horse slaughter operations. Those operations are authorized by FSIS's grant of inspections, as mandated under FMIA, not the Directive. The legally relevant cause of any environmental impacts from the horse slaughter operations at issue in this litigation

is Congress's requirement that FSIS grant inspections to qualifying facilities, and FSIS's Directives system cannot convert a non-discretionary grant of inspection into a discretionary grant of inspection. NEPA therefore does not apply to the Directive, and Plaintiffs' challenge to the Directive must fail.

If the Court finds that FSIS violated NEPA in issuing the Directive, then the Court is obligated to narrowly tailor its relief to address only the deficiencies found. Here, the proper remedy is remand of the Directive without vacatur. FSIS can readily cure any defect the Court may find in FSIS's explanation for invoking a CE for the Directive. Remand of the Directive would not impact the grants of inspection, which FSIS was obligated to issue with or without the Directive.

STANDARDS OF REVIEW

I. JUDICIAL REVIEW UNDER THE ADMINISTRATIVE PROCEDURE ACT

Because NEPA does not provide for a private right of action, the APA, 5 U.S.C. §§701-706, provides the basis for judicial review for challenges to final agency actions under NEPA. *Utah v. Babbitt*, 137 F.3d 1193, 1203 (10th Cir. 1998). "The scope of review under the [APA] is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Under the "arbitrary and capricious" standard, "administrative action is upheld if the agency has 'considered the relevant factors and articulated a rational connection between the facts found

and the choice made.'" *Friends of Endangered Species v. Jantzen*, 760 F.2d 976, 982 (9th Cir. 1985) (quoting *Balt. Gas & Elec. Co. v. Natural Res. Def. Council*, 462 U.S. 87, 105 (1983)); *Airport Neighbors Alliance v. United States*, 90 F.3d 426, 429 (10th Cir. 1996). The court's role is solely to determine whether "the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 416 (1971).

This standard is "exceedingly deferential." *Fund for Animals, Inc. v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996). "While we may not supply a reasoned basis for the agency's action that the agency itself has not given, we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974) (citations omitted); *see also Friends of the Earth v. Hintz*, 800 F.2d 822, 831 (9th Cir. 1986) ("The court may not set aside agency action as arbitrary or capricious unless there is no rational basis for the action."). "The [agency's] action . . . need be only a reasonable, not the best or most reasonable, decision." *Nat'l Wildlife Fed'n v. Burford*, 871 F.2d 849, 855 (9th Cir. 1989).

In deciding disputes that involve primarily issues of fact that "'require[] a high level of technical expertise,' [the court] must defer to 'the informed discretion of the responsible federal agencies.'" *Marsh*, 490 U.S. at 377 (quoting *Kleppe v.*,

427 U.S. at 412); *see also Balt. Gas*, 462 U.S. at 103 ("When examining this kind of scientific determination . . . a reviewing court must generally be at its most deferential."). "Deference to the agency is especially strong where the challenged decisions involve technical or scientific matters within the agency's area of expertise." *Utah Envtl. Cong. v. Russell*, 518 F.3d 817, 824 (10th Cir. 2008) (citing *Marsh*, 490 U.S. at 378). Thus, when dealing with the complex technical issues relating implementation of FMIA, a federal agency such as FSIS "must have discretion to rely on the reasonable opinions of its own qualified experts." *Marsh*, 490 U.S. at 378.

ARGUMENT

I. NEPA DOES NOT APPLY TO USDA'S DECISIONS TO GRANT INSPECTIONS TO SLAUGHTER FACILITIES UNDER FMIA

A. FSIS Lacks Sufficient Discretion In Granting Inspections At Horse Slaughter Facilities Under FMIA To Trigger A NEPA Obligation

"The touchstone of whether NEPA applies is discretion." *Citizens Against Rails-to-Trails v. Surface Transp. Bd.*, 267 F.3d 1144, 1151 (D.C. Cir. 2001). Because FMIA mandates that FSIS grant inspections of the slaughter of amendable species if a facility meets the conditions of eligibility established by FMIA, FSIS lacks sufficient discretion over its actions to weigh environmental considerations. Therefore, the environmental review provisions of NEPA do not apply, and Plaintiffs cannot prevail on the merits of their claims.

For NEPA to apply, a federal agency must be able to select an environmentally preferable alternative (even if that alternative is the "no-action" alternative of denying a proposal) or to impose conditions to mitigate environmental concerns. *Citizens*, 267 F.3d at 1151. Where a federal agency has no such discretion, it would be pointless to conduct an analysis of alternatives--the the "heart" of an EA or an EIS. *See* 40 C.F.R. §1502.14. Accordingly, the Tenth Circuit has held that "NEPA compliance is unnecessary where the agency action at issue involves little or no discretion on the part of the agency." *Sac & Fox Nation of Mo. v. Norton*, 240 F.3d 1250, 1262 (10th Cir. 2001).

FSIS explained in its decisions granting inspections at the facilities at issue here that granting such an inspection is not subject to the requirements of NEPA:

> When a federal agency's action is merely ministerial as opposed to discretionary and the agency lacks discretion to affect the outcome of its action, there is no . . . trigger[for] NEPA requirements. A grant of federal inspection under the FMIA is purely ministerial because, if 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 FMIA 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 FMIA is not . . . subject to NEPA requirements.

AR0002469 (Valley Meat); AR0003283-84 (Responsible Transportation); AR0004870 (Rains). As a result of this limited authority, "FSIS inspectors will not have any authority or control over the day-to-day operations of the [] 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 has reasonably determined that its authority and discretion under FMIA are limited.[2] Through FMIA, Congress has directed 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, 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," 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

[2] A federal agency's interpretation of its authorities and its determination of whether NEPA applies to its actions are entitled to judicial deference. *See, e.g.*, *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843-44 (1984) (holding that judicial review of an administrative agency's construction of the statutes that it administers is limited and deferential); *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1070 (9th Cir. 2002) ("An agency's threshold decision that certain activities are not subject to NEPA is reviewed for reasonableness.").

in connection with slaughter in the slaughtering establishments inspected under this chapter." 21 U.S.C. §603(b) (emphasis added). FMIA further requires that FSIS "shall" 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.

If there were any question from FMIA's plain language that Congress intended to limit FSIS's discretion by requiring that FSIS "shall" provide inspectors, the legislative history for FMIA eliminates all doubt. The House and Senate Reports for the 1967 Amendments to FMIA both indicate that 21 U.S.C. §603(a), or "Section 3", of FMIA 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* Exhibit A hereto at 33; Exhibit B hereto at 26. The House Report states that this amendment would "[m]ake ante mortem inspection mandatory rather than permissive." Exhibit A at 6; *see also id.* at 26 (same). The Senate Report elaborates on this change:

> 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.

Exhibit B at 9 (emphasis added). Plaintiffs' attempts to deny that "shall means shall" and to argue that FSIS enjoys discretion in granting inspections are contrary to both the plain language of FMIA *and* its legislative history.

The Supreme Court has held that mandatory statutory language such as that contained in FMIA directing a federal agency to take a certain action precludes obligations under NEPA and similar federal statutes. In *Public Citizen*, the Supreme Court rejected a claim that a federal agency, the Federal Motor Carrier Safety Administration ("FMCSA"), violated NEPA when it promulgated application and safety rules for Mexican motor carriers entering the United States without analyzing the environmental impacts of allowing the Mexican trucks to cross the border, because the rules were a legal prerequisite to the President's lifting a moratorium on the entry of the trucks. 541 U.S. at 765-66. The flaw in the plaintiffs' argument, the Supreme Court explained, was that FMCSA had no authority to "countermand the President's lifting of the moratorium or otherwise categorically exclude Mexican motor carriers from operating within the United States," because the agency's governing statute provided that FMCSA "'*shall* register a person to provide transportation . . . as a motor carrier if [it] finds that the person is willing and able to comply with' the safety and financial responsibility requirements established by DOT [Department of Transportation]." *Id.* at 766 (quoting 49 U.S.C. §13902(a)(1)) (emphasis and alterations in original). Thus, if a

Mexican carrier satisfied this provision and FMCSA refused to authorize the carrier for cross-border services, the agency "would violate §13902(a)(1)." *Id.*

Because the agency had "no authority" under this provision to prevent the environmental effects caused by Mexican trucks by preventing the Mexican carriers from entering the United States, the Supreme Court held that FMCSA was not required to analyze those effects in an EIS, since "FMCSA simply lacks the power to act on whatever information might be contained in the EIS." *Public Citizen*, 541 U.S. at 768. "Put another way, the legally relevant cause of the entry of the Mexican trucks [for NEPA purposes] is not FMCSA's action, but instead the actions of the President in lifting the moratorium and those of Congress in granting the President this authority *while simultaneously limiting FMCSA's discretion*." *Id.* at 769 (emphasis in original omitted, emphasis added). Here, as in *Public Citizen*, the legally relevant cause of Defendant-Intervenors' horse slaughter operations for NEPA purposes is not FSIS's grants of inspection, which the agency has no authority to deny to qualifying applicants, but the actions of Congress in lifting the funding moratorium while limiting FSIS's discretion in FMIA. *See also id.* at 769 ("It would not . . . satisfy NEPA's 'rule of reason' to require an agency to prepare a full EIS due to the environmental impact of an action it could not refuse to perform.").

The Supreme Court followed *Public Citizen* with another decision that is also dispositive here. In *NAHB*, the Supreme Court rejected a claim that the EPA violated the ESA by failing to analyze impacts on endangered species from EPA's decision to grant a State permitting authority pursuant to the Clean Water Act. 551 U.S. at 649-50. The underlying provision of the Clean Water Act "provides, without qualification, that the EPA '*shall* approve' a transfer application unless it determines that the State lacks adequate authority to perform the nine functions specified in the section." *Id.* at 661 (quoting 33 U.S.C. §1342(b)) (emphasis added). Noting that Congress' "'use of a mandatory 'shall' . . . impose[s] discretionless obligations,'" the Supreme Court concluded that "[b]y its terms, the statutory language is mandatory and the list exclusive; if the nine specified criteria are satisfied, the EPA does not have the discretion to deny a transfer application." *Id.* (citation omitted). In other words, "[i]f the criteria are met, the transfer must be approved." *Id.* at 651.

Because EPA lacked discretion, the Supreme Court held that the agency's decision in granting qualifying States permitting authority under this provision did not trigger any obligations under the ESA. "Since the transfer of . . . permitting authority is not discretionary, but rather is mandated once a State has met the criteria set forth in §402(b) of the [Clean Water Act], it follows that a transfer of . . . permitting authority does not trigger [ESA] requirements." *Id.* at 673. Even

though the ESA "unlike NEPA, imposes a substantive (and not just a procedural) statutory requirement," the Supreme Court drew support for its holding from "the basic principle announced in *Public Citizen*--that an agency cannot be considered the legal 'cause' of an action that it has no statutory discretion *not* to take." *Id.* at 667-68 (emphasis in original).

Because FMIA *requires* that FSIS "shall" grant inspections to facilities that meet applicable humane handling and food safety requirements, 21 U.S.C. §§603, 604, FSIS lacks discretion to deny a grant of inspection on environmental grounds, to choose among alternatives in order to minimize environmental impacts, or to condition a grant of inspection on the mitigation of environmental impacts. In accordance with *Public Citizen* and *NAHB*, then, FSIS correctly determined that NEPA does not apply to its grants of inspection under FMIA.

In accordance with FMIA, USDA and FSIS have promulgated detailed regulations governing the slaughter of all amenable species, including equines, which must be subject to inspection under FMIA. *See* 9 C.F.R. §300.1 through §500.8. Consistent with the limited authority and jurisdiction granted to FSIS under FMIA, these regulations focus on ensuring that animals are slaughtered humanely and that the meat products produced therefrom are unadulterated. *See, e.g.*, 9 C.F.R. §305.3 ("Inspection shall not be inaugurated if an establishment is not in sanitary condition. . . ."). Pursuant to 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 FMIA 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) ("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 [FMIA implementing regulations]."") (emphasis added). FSIS is not authorized to deny the application (or to condition the granting of the application) based on a consideration and weighing of potential environmental impacts from the operation of the facility.

FSIS's authority and discretion are narrowly circumscribed by FMIA, and it is well settled that NEPA does not enlarge that discretion.[3] Because FMIA limits the discretion of FSIS and mandates approval of grants of inspection for facilities meeting FMIA eligibility requirements, environmental considerations pursuant to a NEPA analysis could not have changed FSIS's decision.

[3] *See, e.g.*, *S. Coast Air Quality Mgmt. Dist. v. F.E.R.C.*, 621 F.3d 1085, 1092 (9th Cir. 2010) ("NEPA may not be used to broaden [a federal agency's] congressionally-limited role."); *Natural Res. Def. Council, Inc. v. EPA*, 822 F.2d 104, 129 (D.C. Cir. 1987) ("NEPA, as a procedural device, does not work a broadening of the agency's substantive powers."); *Cape May Greene, Inc. v. Warren*, 698 F.2d 179, 188 (3d Cir. 1983) ("[NEPA] does not expand the jurisdiction of an agency beyond that set forth in its organic statute.").

Plaintiffs argue that the court in *Humane Society of the United States v. Johanns*, 520 F. Supp. 2d 8 (D.D.C. 2007), has already held that FSIS's inspections of horse slaughter facilities are subject to NEPA review. But *Johanns* is inapposite. At issue in *Johanns* was an Interim Final Rule that FSIS promulgated to allow horse slaughter facilities to voluntarily obtain and pay for FSIS inspections on a "fee-for-service" basis during the pendency of Congress's funding moratorium for such inspections under FMIA. *Id.* at 13. The Interim Final Rule was not adopted under mandatory requirements of FMIA but was, according to the court, "an entirely new regulatory framework for [FSIS's] ante-mortem inspections," *id.* at 28, promulgated under the authority of the Agricultural Marketing Act ("AMA"), 7 U.S.C. § 1621. *Johanns*, 520 F. Supp. 2d at 13. Thus, while the *Johanns* court noted FSIS's lack of discretion under FMIA, the court held that "promulgation of the Interim Final Rule was within [FSIS's] discretion" because FSIS was not "required" to promulgate the Rule under the AMA. *Id.* at 27. Thus, the court concluded, *Public Citizen* was distinguishable since the Interim Final Rule was "the 'legally relevant cause' of the environmental effects of the horse slaughter facilities after the FY 2006 Amendment [halting federal funding for inspections under FMIA] went into effect." *Id.* Thus, in contrast to FSIS's nondiscretionary duty to grant inspections at qualifying facilities here as dictated by Congress through FMIA, the *Johanns* court held that NEPA applied to FSIS's

discretionary decision under the AMA to allow horse slaughter facilities to operate. *Id.*

Because FMIA does not afford FSIS such discretion here, an EIS could not meaningfully inform or affect FSIS's grants of inspections for the Valley Meat, Responsible Transportation, and Rains facilities, and FSIS reasonably and correctly concluded that NEPA did not apply. *See, e.g.*, *Sac & Fox Nation*, 240 F.3d at 1262-63 (holding that a federal agency reasonably concluded that NEPA did not apply to its decision because a NEPA analysis would have been "pointless" since the analysis could not have had an impact on the decision as a result of the agency's lack of discretion). Plaintiffs' NEPA challenges to FSIS's grants of inspection are without merit and must be denied.

II. EVEN IF NEPA APPLIED TO GRANTS OF INSPECTION UNDER FMIA, USDA PROPERLY INVOKED ITS CATEGORICAL EXCLUSION IN ACCORDANCE WITH NEPA

Even if NEPA did apply to FSIS's grants of inspection for the Valley Meat, Responsible Transportation, and Rains facilities, Plaintiffs still cannot succeed on their NEPA claims. FSIS satisfied any NEPA obligations by determining that its actions fell within USDA's established CE for FSIS actions and that no extraordinary circumstances precluded use of that CE.

USDA's NEPA regulations state:

> The USDA agencies and agency units listed in paragraph (b) of this section conduct programs and activities that have been found to have

> no individual or cumulative effect on the human environment. The USDA agencies and agency units listed in paragraph (b) of this section are excluded from the requirements of preparing procedures to implement NEPA. Actions of USDA agencies and agency units listed in paragraph (b) of this section 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 C.F.R. §1b.4(a). FSIS is one of the USDA agencies expressly identified for coverage under this categorical exclusion. *See id.* §1b.4(b)(6) (listing "Food Safety and Inspection Service").

Although FSIS in the first instance determined that NEPA did not apply to its grants of inspection, FSIS invoked this CE under the NEPA process and conducted a thorough assessment to ensure that no extraordinary circumstances were present that would preclude use of the CE for the three facilities in question. *See* AR0002466-76; AR0003281-89; AR0004868-78. Fore example, FSIS's CE decision for Valley Meat specifically assessed Plaintiffs' central claim that Valley Meat 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 that are destined for human consumption. *See* Pls.' Br., ECF No. 170 at 12-13. As explained in the CE for Valley Meat, 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. AR0002469-71. *See also* AR0003285-86 (Responsible Transportation CE); AR0004870-71 (Rains CE).

Any meat found to contain such residues will be marked "condemned" and sent to a rendering facility, "thereby ensuring that it endangers neither public health and safety nor the local environment." AR0002471. *See also* AR0004444 (Responsible Transportation has engaged the services of a rendering facility); AR0004878 (same for Rains).

Because of this screening process, as well as overlapping layers of federal, state, and local laws regulating Valley Meat's operations, FSIS reasonably 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." AR0002476. *See also* AR0003289 (Responsible Transportation); AR0004878 (Rains). From an environmental impact standpoint, there is nothing unique or extraordinary about the proposed operations at the three facilities. AR0003289 (Responsible Transportation); AR0004878 (Rains). Indeed, if evidence suggests 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. AR0001855-56; Engeljohn Decl. ¶¶10, 16.

FSIS concluded that no extraordinary circumstances exist in issuing the grants of inspection to Valley Meat, Responsible Transportation, and Rains. AR0002476; AR0003289; AR0004878. The Court should defer to FSIS's analyses[4] and determination that invoking its CE for the grants was appropriate. "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). "When reviewing an agency's interpretation and application of its categorical exclusions under the arbitrary and capricious standard, courts are deferential." *Id.* (footnote and citations omitted).

A. FSIS Properly Determined That For Issuance Of The Grants Of Inspection, No Extraordinary Circumstances Exist Leading To Potential Significant Impacts

Plaintiffs' argument that horse slaughter operations occurring under a grant of inspection by FSIS may significantly affect the environment, Pls.' Br. at 22, is seriously flawed, both legally and factually. In making this argument, Plaintiffs rely heavily on their petition to have FSIS initiate a rulemaking that would declare

[4] Although a "brief statement that a categorical exclusion is being invoked will suffice," *California v. Norton*, 311 F.3d 1162, 1176 (9th Cir. 2002), the CE decision memoranda prepared by FSIS reflect considerable analysis and detail, almost comparable to an EA. *See also* 40 C.F.R. § 1500.4(p) ("Agencies shall reduce excessive paperwork by . . . [u]sing categorical exclusions"); 46 Fed. Reg. 18,026 (Mar. 23, 1981) (CEQ Forty Questions, #36, stating that an EA should be 10-15 pages).

any horse offered for slaughter for human consumption as "U.S. CONDEMNED" unless it is accompanied by full medical records since birth and unless it is individually tested for residue of all potentially dangerous substances. *See* Pls.' Br. at 35; NM Br. at 4. On June 28, 2013, FSIS issued a detailed response denying Plaintiffs' petition because FSIS found "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." AR0001855.

An agency must prepare an EIS when there are substantial questions about whether a project may cause significant effects on the human environment. *Barnes v. U.S. D.O.T.*, 655 F.3d 1134, 1136 (9th Cir. 2011). In reviewing an agency's decision not to prepare an EIS, courts employ an arbitrary and capricious standard requiring a determination as to "whether the agency has taken a 'hard look' at the consequences of its action, based [its decision] on a consideration of the relevant factors, and provided a convincing statement of reasons to explain why a project's impacts are insignificant." *Native Ecosys. Council v. U.S. Forest Serv.*, 428 F.3d 1233, 1239 (9th Cir. 2005) (internal quotations and citations omitted). "Review under this standard is to be searching and careful, but remains narrow, and a court is not to substitute its judgment for that of the agency." *Sierra Club v. Bosworth*, 465 F.Supp.2d 931, 937 (N.D. Cal. 2006). Deference is especially warranted when "reviewing the agency's technical analysis and judgments, based on an evaluation

of complex scientific data within the agency's technical expertise." *Envtl. Defense Ctr., Inc. v. EPA*, 344 F.3d 832, 869 (9th Cir. 2003). *See also Lands Council v. McNair*, 537 F.3d 981, 993 (9th Cir 2008) (en banc) ("We are to be most deferential when the agency is making predictions, within its [area of] special expertise.") (internal citations omitted).

Whether there may be a significant effect on the environment requires the agency to consider two factors: context and intensity. *See* 40 C.F.R. § 1508.27; *Nat'l Parks & Conservation Assoc. v. Babbitt*, 241 F.3d 722, 731 (9th Cir. 2001). Context examines the scope of the agency's action, including the interests affected, while intensity relates to the degree to which the agency action affects the local area. *Id*. Here, Plaintiffs allege that several factors relating to intensity required the preparation of an EA or EIS for issuance of the grants. Pls.' Br. at 20-21, 35. As explained below, none of the significance factors apply here. Plaintiffs have not met their burden to show that the grants pose unknown risks, are highly controversial within the meaning of NEPA, set a precedent for future actions, or threaten violation of other federal or state statutes. In the three CE decisions, FSIS examined the potential impacts from operation of these facilities on environmental and other resources to ensure that there were no unique or extraordinary circumstances that would render the CE inapplicable. AR0002471-76; AR0003285-89; AR0004868-78. Assuming *arguendo* that NEPA applies to

issuance of the grants, FSIS fully satisfied its NEPA obligations in issuing the grants and Plaintiffs' claim fails.

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

First, Plaintiffs argue that the grants of inspection will have significant environmental impacts because they "pose serious risks to public health or safety and unique or unknown health and safety risks." Pls.' Br. at 36. As demonstrated in the administrative record, FSIS considered Plaintiffs' opinions and determined, in its experience and expertise, that these opinions lack merit. The Court should reject Plaintiffs' opinions and defer to FSIS's special expertise in this area.

NEPA regulations do not require an EIS "anytime there is some uncertainty, but, only if the effects of the project are 'highly' uncertain." *Ctr. for Biological Diversity v. Kempthorne*, 588 F.3d 701, 712 (9th Cir. 2009). *See also Envtl. Prot. Info. Ctr. v. U.S. Forest Serv.*, 451 F.3d 1005, 1011 (9th Cir. 2006) (upholding agency's preparation of an EA when predicted harm to spotted owls was not highly uncertain). Courts should grant the agency "great deference as it makes a scientific prediction within the scope of its technical expertise." *Ctr. for Biological Diversity*, 588 F.3d at 712 (upholding agency's preparation of an EA where effects from climate change were uncertain, but not "'highly uncertain'").

Plaintiffs' arguments that the grants pose "unknown safety and health risks" are not supported by the record. Plaintiffs' conclusory assertions, for instance, that

"virtually every American horse" has been administered "most" of the drugs that "federal agencies have gone so far as to expressly prohibit" for use in horses destined for slaughter and human consumption, and that these drugs will thus be present in these horses at the time of slaughter, Pls.' Br. at 35-36, are demonstrably false.[5] Moreover, the only information Plaintiffs offer in support is a citation to Plaintiffs' own petition, which FSIS rejected after careful review. *Id*., citing AR0000017-18; AR0000094-123 (exhibits to Plaintiffs' petition).

However, FSIS--the expert agency in this field--has previously explained that the fact that 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. "Residues do not remain in animals forever; they are eliminated from the body over time," because they are "excreted from the animal's system . . . eventually leaving no detectable residue." AR0001854.

To address concerns about drug residue in meat, FSIS developed the National Residue Testing Program in concert with experts from FDA, EPA, the Agricultural Research Service, the Agricultural Marketing Service, and the Centers for Disease Control and Prevention. Engeljohn Decl. ¶12; AR0000199-200.

[5] Plaintiffs' argument also entirely ignores the tens of thousands of abandoned and feral horses on public lands without owners. AR0000976-1044. Indeed, many of these horses are born on public lands and have never been cared for by a human owner. *Id*.

These experts developed a sampling program for chemical compounds in meat based on prior findings of chemical compounds, veterinary drug inventories, information from investigations, and pesticides. *Id*. The NRP has evolved over time to respond to emerging chemical residue concerns. *Id*. ¶13. The multi-residue method for testing equine tissue is the same as the program for cattle, swine or poultry and can detect up to 52 analytes in muscle, kidney, and liver. *Id*. ¶14. "The drug residues being assessed include those of potential public health concern from all livestock, including equines." *Id*. In other words, FSIS tests for all of the most common analytes found in livestock, including equines. AR0002262 (history of residue testing in horses); AR0001825-52 (Decision Memo on the Development of an Equine Slaughter and Further Processing Inspection Regime).

Moreover, during FSIS's extensive testing of thousands of horses in slaughter facilities from 1997 to 2006, "the number of positive results for each class of drug was exceedingly low, rarely exceeding more than one per year for all drug classes [including phenylbutazone] except antibiotics." Engeljohn Decl. ¶17; AR0002262 ("[H]istorically the occurrence of residues in horses has been *less than* what we find in the cull dairy cow and the bob veal slaughter facility.") (emphasis added). Moreover, "FSIS fully protects consumers from harm by enforcing a zero tolerance (*i.e.*, no detectable levels permitted) policy for substances in horsemeat,"

AR0001854, for which FDA and EPA have not established tolerance levels, and "FSIS condemns the entire carcass of an animal that tests positive for that substance and prohibits its use for human food." *Id*.

Plaintiffs' argument that FSIS tested an "inadequate" number of residues, Pls.' Br. at 38-39, lacks support in the record. FSIS, along with other expert agencies, determined in their experience and expertise that testing for the most common substances will adequately protect public health. AR0001825-52. If tests of the most common substances do not yield positive results, there is no basis to conclude that tests for *uncommon* substances (some of which are cited in Plaintiffs' petition) will yield positive results.

Thus, the underlying premise for Plaintiffs' central NEPA argument--that virtually every horse that enters a slaughter facility will be tainted with dangerous drugs and other dangerous chemicals that may enter the environment after slaughter--is squarely at odds with the science, evidence, expert opinion, and practice.

Plaintiffs also argue that USDA "specifically acknowledges the 'potential public health risks' stemming from the slaughter and sale of contaminated meat." Pls.' Br. at 37 (quoting AR0002471; AR0003285). NEPA, however, permits an agency to disclose potential impacts without automatically triggering the threshold for an EIS. *Native Ecosys. Council*, 428 F.3d at 1240. "An agency must generally

prepare an EIS if the environmental effects of a proposed agency action are highly uncertain." *Id*. (quoting *Nat'l Parks*, 241 F.3d at 731-32.) Information "merely favorable to [plaintiff's] position . . . does not necessarily raise a substantial question about the significance of the project's environmental effects." *Id*.

Here, FSIS simply acknowledges that the potential impacts "may cause concern with segments of the public." AR0002471; AR0003285. This statement merely recognizes that some segments of the public have raised concerns about the safety of horse meat for human consumption. FSIS explain, however, that their policies and procedures address these concerns and why these concerns do not rise to the level of extraordinary circumstances. *Id*. ("A decision to grant federal inspection to Valley Meat will safeguard public health and safety."). Plaintiffs' arguments that issuing grants of inspection involve unique an unknown risks lack merit.

2. Issuing Grants of Inspection Is Not Highly Controversial Within the Meaning of NEPA

Plaintiffs also argue the grants of inspection have significant impacts because they are "highly controversial." Pls.' Br. at 38; NM Br. at 20-21. In this context, controversy "does not mean opposition to a project, but rather a 'substantial dispute about the size, nature, or effect of the action.'" *Hillsdale Envtl. Loss Prevention, Inc. v. U.S. Army Corps of Eng'rs*, 702 F.3d 1156, 1181 (10th

Cir. 2012) (quoting *Middle Rio Grande Conservancy Dist. v. Norton*, 294 F.3d 1220, 1229 (10th Cir. 2002)).

Here, Plaintiffs' general opposition to horse slaughter does not, in and of itself, make the grants highly controversial such that preparation of an EIS is required. *See Anderson v. Evans*, 314 F.3d 1006, 1018-19 (9th Cir. 2002) amended and superseded, 371 F.3d 475 (9th Cir. 2004). If mere disagreement with an agency action was all that was necessary to mandate an EIS, the EA (and CE) process would be meaningless. *Greenpeace Action v. Franklin*, 14 F.3d 1324, 1335 (9th Cir. 1992). Plaintiffs' attempts to generate controversy by misrepresenting USDA's residue testing program fall short.

Plaintiffs' assertion that "USDA's new residue testing plan requires testing only four of each 100 or more horses slaughtered, so that 96 percent of the byproducts of slaughtered horses will flow into the local groundwater and waterways." NM Br. at 20-21, is flawed and grossly misapprehends the process at the slaughter facilities. Under FSIS's Directive, FSIS inspectors will sample "approximately a minimum of four to ten percent of the number of healthy-appearing equines slaughtered each slaughter shift," and "may increase the frequency of residue testing, up to 100%, based on the establishment's compliance history." Engeljohn Decl. ¶16; AR0001855-56. In addition to this random sampling of animals that appear healthy, the inspectors will "sample and test *every*

equine when ante-mortem or post-mortem findings suggest an increased likelihood of recent drug treatment." Engeljohn Decl. ¶16 (emphasis added). Importantly, *regardless of whether an animal has been tested, its inedible "byproducts," including blood, fecally contaminated meat, and diseased tissue will not "flow into the local groundwater and waterways."* For example, at the Valley Meat facility, the inedible portions of all animals slaughtered will be denatured to prevent possible human use and placed in specially-marked containers identified for inedible product and sent to an off-site rendering facility for appropriate destruction. Engeljohn Decl. ¶24; AR0002510; AR0002594-95. Contrary to Plaintiffs' unsupported assertions, NM Br. at 20-21, blood and other inedible byproducts will not be placed in the septic or lagoon system at the facilities and will not enter the environment, particularly on the lands surrounding the slaughter facility. AR0002476; AR0002509; AR0003288-89; AR0004877. Plaintiffs' claims attempting to create controversy lack merit and are at odds with the administrative record evidence. Again, the only expert opinion before the Court is that of FSIS indicating that horse presented for slaughter will not commonly contain violative drug residues and, in any event, the horse byproducts will not enter the environment but will be sent to rendering.

3. The Grants Of Inspection Do Not Threaten Violation Of Federal Or State Law

Plaintiffs argue that granting inspections at the Valley Meat facility will trigger one of the significance factors under NEPA regulations, alleging violations of the Endangered Species Act and state environmental laws. Plaintiffs' claims lack merit and record support.

Plaintiffs argue that the grant to Valley Meat "implicate[s] the degree to which the action may adversely affect an endangered or threatened species or its habitat." NM Br. at 21-22 (citing 40 C.F.R. §1508.27(b)(9)). To the contrary, FSIS made a reasoned and well-supported determination that the grant of inspection would not have any direct or indirect impact on any federal or state listed endangered species. AR0002473; AR0003287 (Responsible Transportation CE); AR0004876 (Rains CE). The record shows that FSIS initiated informal consultation with FWS, pursuant to the Endangered Species Act, AR0002542-51, and that FWS concurred in FSIS's determination that the grants of inspection would have no impact on any listed species. *Id*. Plaintiffs have not presented any record evidence that calls into question the agencies' expert determinations. In fact, Plaintiffs do not even identify which endangered species may be at issue, and do not present any argument regarding this factor with respect to the Iowa or Missouri facilities. NM Br. at 21-22. Plaintiffs thus fall far short of demonstrating

that the grants may adversely affect an endangered or threatened species or its habitat.

Plaintiffs also claim that USDA is aware that three previous horse slaughter facilities in the United States "wreaked environmental havoc on their host communities, which included violations of environmental laws and regulations." Pls.' Br. at 41. The only evidence in the record regarding these allegations is contained in Plaintiffs' petition, which was accompanied by declarations from laypeople who claimed that operations at three now-closed facilities (Beltex, Cavel and Dallas Crown) resulted in environmental harms. However, the record contains no declarations from experts or other evidence of a comparable nature that support Plaintiffs' allegations or that establish that there were any significant violations of environmental laws and regulations during the operative periods for Beltex, Cavel, and Dallas Crown.

Moreover, Plaintiffs offer no support in their brief for the proposition that the Court may impute the alleged past environmental harms of these other facilities onto future actions by the facilities at issue in this litigation. At the hearing on Plaintiffs' motion for temporary restraining order, Plaintiffs cited *Reed v. Salazar*, 744 F.Supp.2d 98 (D.D.C. 2010), to support this argument, but that case is easily distinguishable. In *Reed*, the plaintiffs challenged a 2008 annual funding agreement between FWS and the Confederated Salish & Kootenai Tribes for

management of the National Bison Range Complex, which is a part of the National Wildlife Refuge System. *Id.* at 100. The Tribe and FWS had entered into a similar agreement in 2005. *Id*. at 105. The plaintiffs claimed that FWS violated NEPA, arguing that the agency had failed to properly invoke a CE and failed to analyze extraordinary circumstances. *Id*. at 115. The plaintiffs pointed to evidence in the record showing the Tribe's poor performance in meeting the environmental standards required under the 2005 funding agreement. *Id*. at 117. The court found that FWS's failure to explain its application of a CE, "in light of substantial evidence in the record of past performance problems by the [Tribe]" was arbitrary and capricious. *Id*. at 118.

Thus, the court's finding involved the same party (the Tribe) with whom FWS had partnered in the past and who was allegedly responsible for past harms. That is not the situation in this case. Here, Plaintiffs rely on past harms that were allegedly committed by three companies no longer in existence and which have no responsibility for management of the three facilities at issue here. Indeed, the facilities on which Plaintiffs seek to rely have been closed since 2007. ECF No. 66-1, Engeljohn Decl. ¶¶20-21.

Even assuming some of Plaintiffs' allegations about past environmental harms are accurate, FSIS has explained that the Valley Meat and Responsible Transportation facilities will not utilize the same waste discharge methods as the

previous facilities. Engeljohn Decl. ¶¶20, 23. The three now-closed facilities discharged their waste water into municipal waste water systems. *Id*. ¶20. In contrast, Valley Meat, Responsible Transportation, and Rains Natural Meats will discharge wastewater into septic tanks and lagoon systems that are wholly located on their premises. *Id*. ¶23. All three companies have attested that they will not discharge into navigable waters. AR0002567; AR0003290-91; AR0004808.[6]

Finally, Plaintiffs argue that the potential violation of law significance factor is implicated because "USDA knows that [Valley Meat] has repeatedly committed gross violations of New Mexico environmental laws and regulations when it was in the business of slaughtering cattle." Pls.' Br. at 40-41. This claim is exaggerated and inaccurate. USDA is aware of only one environmental violation at Valley Meat in its twenty year history as a cattle slaughter facility. That incident involved problems with a compost pile wholly contained on Valley Meat's property--an

[6] In addition, Valley Meat has provided FSIS with its Groundwater Permit Renewal Application and supporting documents, AR0002574-607, and a No Exposure Certification for Exclusion from National Pollutant Discharge Elimination System ("NPDES") Stormwater Permitting, AR0002608-13. *See also* AR0002472-73. Responsible Transportation has provided FSIS with a 5907 Water Use Permit Renewal, AR0003356-61, Stormwater NPDES General Permit, AR0003362-3365, an Iowa Operation Permit for a Land Application System, AR0003367-88, and a Public Water Supply Operation Permit Renewal and Permit, AR0003343-3354. Rains Natural Meats has provided FSIS with an attestation that it will have no discharges into navigable waters, as defined by the Clean Water Act, AR0004808, and certification of its waste management facility and lagoon construction permit, AR0004599-601, and an effluent agreement with the City of Gallatin, AR0004790.

incident which USDA itself reported to the New Mexico Environment Department. AR0002766-69. Valley Meat took corrective actions, New Mexico terminated its enforcement action, and Valley Meat does not presently have a composting permit. Instead, it has contracted with a rendering facility for disposal of the solid waste materials, including the blood and offal. Engeljohn Decl. ¶24; AR0002535; AR0002547; AR2000743-53. The history of this single corrected incident does not establish that Valley Meat "has repeatedly committed gross violations" of environmental laws.

In short, the present operations are run by different companies and in different ways than the prior horse slaughter operations on which Plaintiffs base their allegations. Those prior operations lack any evidentiary weight, and Plaintiffs have failed to show that the grants of inspection have significant environmental impacts based on potential violations of federal or state law.

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

Plaintiffs assert that the grants of inspection have a significant environmental impact because they establish a precedent for future actions with significant effect. Pls.' Br. at 39-40 (citing 40 C.F.R. § 1508.27(b)(6)). In order to be significant based on precedential impact under 40 C.F.R. § 1508.27(b)(6), agencies must evaluate "[t]he degree to which the effects the action may establish a

precedent for future actions with significant effects or represent[] a decision in principle about a future consideration." *Id*.

Plaintiffs argue that FSIS has applications for grants of inspection for three other facilities, and that the issuance of the Valley Meat, Responsible Transportation, and Rains grants set a precedent for these three other facilities. Pls.' Br. at 39-40. FSIS has already explained that these 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 their first submissions to FSIS, each occurring more than one year ago. Engeljohn Decl. ¶7. Thus, 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--when and if they are received--will be treated. There is thus no basis for a conclusion that the grants of inspection at issue here are significant because of any precedent they set for future applications.

5. FSIS Is Not Required To Analyze The Cumulative Impacts Of The Grants

Plaintiffs argue that the Agency failed to analyze cumulative impacts of issuing the grants of inspection to Valley Meat, Responsible Transportation and

Rains, and failed to consider the cumulative impacts of issuing these grants combined with issuing grants to future facilities. NM Br. at 25-26. An analysis of cumulative impacts of the three facilities at issue or any hypothetical future facilities is not required here. By definition, a categorical exclusion is "a category 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." 40 C.F.R. § 1508.4. Consequently, the Tenth Circuit has unequivocally held that the cumulative effects analysis required by 40 C.F.R. §1508.7 need not be performed when a CE is applied. *See Utah Envtl. Cong. v. Bosworth*, 443 F.3d 732, 741 (10th Cir. 2006) ("the cumulative effects analysis required by an [EA] need not be performed" with a CE); *Ctr. for Biological Diversity v. Salazar*, 706 F.3d 1085, 1096-97 (9th Cir. 2013); *Nat'l Trust for Historic Pres. v. Dole*, 828 F.2d 776, 781 (D.C. Cir. 1987). Indeed, requiring FSIS to conduct a cumulative impacts analysis every time it applied a CE would be redundant and "inconsistent with the efficiencies that the abbreviated categorical exclusion process provides." *Ctr. for Biological Diversity*, 706 F.3d at 1097; *see also* 75 Fed. Reg. 75,630, 75,630 (Dec. 6, 2010) (explaining that the documentation for applying a CE should be "as concise as possible to avoid unnecessary delays and administrative burdens for projects and programs"). Therefore, a cumulative impacts analysis was not required.

Even if a cumulative impacts analysis was required, FSIS's analysis of extraordinary circumstances, as set forth in the CE decisions, is sufficient to confirm that there are no significant effects attributable to the grants. A cumulative impact is defined as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions." 40 C.F.R. §1508.7. Cumulative impacts are thus the additive effects of multiple projects interacting to create a great effect. But Plaintiffs allege and complain only about the highly localized effects at each of the facilities, such as odors and discharges into the local waterways. Plaintiffs fail to offer any explanation how widely scattered facilities in different states with only localized environmental impacts will have *any*, let alone significant, cumulative effects.

Plaintiffs also argue that FSIS was required to disclose and analyze impacts of issuing grants to Valley Meat, Responsible Transportation, and Rains Natural Meats combined with the impacts of any grants to hypothetical future facilities. The Tenth Circuit has held that agencies are not required to consider "speculative" impacts or actions, only "reasonably foreseeable future actions." *Wyoming v. U.S. Dep't of Agric.*, 661 F.3d 1209, 1253 (10th Cir. 2011). *See also Wilderness Workshop v. BLM*, 531 F.3d 1220, 1228-31 (10th Cir. 2008) (holding that NEPA did not require the agency to analyze the impacts of future actions that were

"speculative" or not "imminent" connected actions); *Sierra Club v. Lujan*, 949 F.2d 362, 368 (10th Cir. 1991) ("NEPA does not require an agency to consider the environmental effects that speculative or hypothetical projects might have on a proposed project."). *See also Safeguarding The Historic Hascom Area's Irreplaceable Res., Inc. v. FAA*, 651 F.3d 202, 218 (1st Cir. 2011) ("For NEPA purposes, an agency need not speculate about the possible effects of future actions that may or may not ensue."); *Envtl. Prot. Info. Ctr.*, 451 F.3d at 1014 (holding that if not enough information is available to give meaningful consideration now, an agency decision may not be invalidated based on the failure to discuss an inchoate, yet contemplated, project.).

That was precisely the situation here. Not enough information is available about the three outstanding applications for grants of inspection for FSIS to give meaningful consideration to their potential cumulative impacts. As explained above, none of the three applicants have pursued their applications since their submission over one year ago. Thus, it is highly speculative that these facilities will ever operate, nor is there any evidence that these widely-dipersed facilities will have synergistic, cumulative impacts. FSIS was not required to consider the

cumulative impacts of these facilities and the Valley Meat, Responsible Transportation, and Rains CE decisions.[7]

6. FSIS Was Not Influenced By Improper Political Considerations

Plaintiffs argue that USDA "seriously consider[ed] politics in making its decision to authorize horse slaughter without undertaking NEPA review." Pls.' Br. at 17, 45-46. The record clearly shows this argument is meritless.

To support this argument, Plaintiffs selectively cite several pages of USDA's Decision Memorandum for the Under Secretary regarding Plaintiffs' petition. AR0001820-52. The portions Plaintiffs cite concern a discussion of various factors to be considered in determining whether to grant Plaintiffs' petition--not a discussion of whether to prepare an environmental analysis. AR0001827-28. The document asks:

> [W]hether, 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 a rulemaking to require such a history?

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[7] The various grants of inspection (both existing and inchoate) also are plainly not "connect actions," as they have no dependence on one another. As the Tenth Circuit has stated, "connected actions" are projects that "'cannot or will not proceed unless other actions are taken previously or simultaneously' and constitute 'interdependent parts of a larger action and depend on the larger actions for their justification.'" *Airport Neighbors Alliance, Inc. v. United States*, 90 F.3d 426, 431 (10th Cir. 1996) (citing 40 C.F.R. §1508.25(a)(1)).

AR0001827. The document states that there are several factors that bear on the 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.
>
> The second factor is largely political. FSIS is already seen in some quarters 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.

Id. at 1827-28. The document Plaintiffs cite is merely a discussion of potential options, arguments, and considerations relating to the reinstatement of equine inspections. It clearly evidences USDA's careful deliberation of these issues,

including those raised in Plaintiffs' petition, and does not concern questions about preparation of NEPA documentation. And it certainly does not show that USDA decided for "political" reasons not to prepare an EIS. Plaintiffs' allegations of improper political considerations informing the NEPA process are entirely without merit or support in the record.

In contrast to Plaintiffs' obviously flawed arguments about the potential effects of horse slaughter activities on the environment, FSIS reasonably and rationally invoked USDA's CE for its grants of inspection at the Valley Meat, Responsible Transportation, and Rains facilities, relying on the technical opinions of its qualified experts to determine that unique and extraordinary circumstances did not exist that would indicate the potential for significant environmental impacts, as discussed above. These determinations are entitled to substantial deference. "[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, Plaintiffs' NEPA claims fail.

III. USDA'S INTERNAL DIRECTIVE INFORMING ITS EMPLOYEES ON HOW TO PROPERLY CONDUCT HORSE SLAUGHTER INSPECTIONS IS NOT SUBJECT TO JUDICIAL REVIEW OR TO NEPA REQUIREMENTS

A. Directive 6130.1 Is Not A "Final Agency Action" For Purposes Of Judicial Review Under The APA

As non-binding internal agency guidance that does not require any third party to do or refrain from doing anything, Directive 6130.1 does not constitute a "final agency action" subject to judicial review under the APA. Plaintiffs' challenge to the Directive therefore must be dismissed.

As noted above, NEPA claims may be reviewed only pursuant to the APA. *Utah*, 137 F.3d at 1203. As a waiver of sovereign immunity for claims against the United States, the APA limits what federal agency activities may be challenged in federal court. *High Country Citizens Alliance v. Clarke*, 454 F.3d 1177, 1181 (10th Cir. 2006) ("APA serves as a limited waiver of sovereign immunity."). The APA limits judicial review to "final agency action." 5 U.S.C. §704. Thus, to successfully invoke this Court's jurisdiction under the APA, Plaintiffs must "satisfy the 'statutory standing' requirements of the APA" and "must establish that Defendants took 'final agency action for which there is no other adequate remedy in court.'" *Wyoming v. U.S. Dep't of Interior*, 360 F.Supp.2d 1214, 1236 (D. Wyo. 2005) (quoting *Utah*, 137 F.3d at 1203).

"As a general matter, two conditions must be satisfied for agency action to be 'final': First, the action must mark the 'consummation' of the agency's decisionmaking process, . . . it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotations and citations omitted).

At a minimum, Directive 6130.1 does not satisfy the second requirement of the test of final agency action because it only outlines and summarizes the general procedures FSIS inspectors will follow when undertaking inspections at facilities that have qualified for inspections under FMIA. The underlying provisions of FMIA and its implementing regulations establish the requirements for inspections. The Directive--along with numerous other Directives and "Notices"--are merely internal guides to aid agency personnel.

Even if the Directive can be appropriately characterized as a "decision" by FSIS as to how to conduct inspections under FMIA, such a characterization does not render the Directive a final agency action. The Directive plainly does not constitute an action by which rights or obligations have been determined, or from which legal consequences will flow. The Directive itself has no legal impact on Plaintiffs or their members, but merely sets forth instructions for ensuring post-grant inspections satisfy FMIA requirements. The adverse consequences to the

environment alleged by Plaintiffs accrue, if at all, only after a grant of inspection has been approved. When FSIS approves a particular grant of inspection, Plaintiffs may challenge the agency's decision, as they have here for the grants to Valley Meat, Responsible Transportation, and Rains, and complain that FSIS has not satisfied the procedural obligations of NEPA with respect to those grants. The Directive itself establishes no rights or legal obligations, particularly with respect to Plaintiffs.

In asserting that the Directive is final agency action, Plaintiffs focus on their claim that the Directive is "binding" on agency employees, or has legal consequences for the slaughter facilities. Pls.' Br. at 28 and n.15. The critical inquiry, however, is not whether the Directive is binding on employees or has legal consequences for others, but whether the Directive determines "rights or obligations" or has "legal consequences" *for Plaintiffs*. *See, e.g., Mobil Exploration*, 180 F.3d at 1199 (noting that the second prong of the *Bennett* test "asks whether the letter imposes legal obligations or consequences on Plaintiffs"); *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 417 F.3d 1272, 1278 (D.C. Cir. 2005) ("In other words, an agency action is final if, as the Supreme Court has said, it is 'definitive' and has a 'direct and immediate . . . effect on the day-to-day business' *of the party challenging it*.") (quoting *FTC*, 449 U.S. at 239) (emphasis added); *Public Serv. Co. of Colo. v. EPA*, 225 F.3d 1144 (10th Cir.

2000) (finding EPA opinion letters did determine any rights or obligations of plaintiff). *See also* William Funk, *A Primer on Nonlegislative Rules*, 53 Admin. L. Rev. 1321, 1334 (2001) ("Courts do not always appreciate [the] distinction between finally deciding rights and obligations of persons, which cannot be done without legislative rulemaking, and providing mandatory directions to subordinates in an agency, which should be permitted without legislative rulemaking."). Here, the Directive had no effect on Plaintiffs whatsoever, and certainly no "direct" legal effect. Indeed, Plaintiffs themselves allege that the Directive only had any effect on them because FSIS "relied" on the Directive in its NEPA analyses. *See* Pls. Br.' at 28 ("That USDA incorporated the Directive into its CE Memos and expressly relied on it in granting inspection demonstrates that the new program is 'definite' and has a 'direct and immediate' effect."). The allegation that the Directive had no effect, let alone any direct legal effect, until FSIS relied on it in the subsequent intervening individual grants of inspections demonstrates that the Directive itself has no legal consequences.

In any event, the internal agency guidance in the Directive is not legally binding on any party, including the facilities or FSIS. *See, e.g.*, *Schweiker v. Hansen*, 450 U.S. 785, 789-90 (1981) (holding that federal agency's internal instruction manual "is not a regulation[,] has no legal force, and it does not bind the [federal agency]"); *W. Radio Services Co., Inc. v. Espy*, 79 F.3d 896, 901 (9th

Cir. 1996) (holding that the USDA Forest Service's Manual and Handbook governing the actions of agency employees "do not have the independent force and effect of law"). The Directive does not purport to impose any obligation or restriction on horse slaughter applicants themselves.[8] Moreover, the Directive is not binding on either the agency or third parties because it is a compilation of guidelines, not substantive rules; was not promulgated pursuant to the "notice and comment" procedures of the APA; and is not published in the Code of Federal Regulations. *See id.* at 901 (listing factors to determine if agency pronouncements have the independent force and effect of law); *River Runners for Wilderness v. Martin*, 593 F.3d 1064, 1073 (9th Cir. 2010) (holding that National Park Service management policies "are not enforceable" because they "do not prescribe substantive rules, nor were they promulgated in conformance with the procedures of the APA").

Unlike regulations, FSIS Directives are terminable at will by the agency, without public notice or any procedure required by law, because FSIS Directives are not promulgated in that manner in the first instance. AR0004870-71. Indeed,

[8] This Court found that the Directive had legal consequences because "violations of the residue testing standards may result in a regulatory enforcement action." TRO, ECF No. 125 at 3. The Directive does not establish any residue testing standards, and any "regulatory enforcement action" of a third party would not be, and could not be, based on a violation of the Directive (which, as discussed, is not legally enforceable), but rather based on an underlying provision of FMIA and its implementing regulations.

FSIS's Directives like Directive 6130.1 must be "*based on* meat, poultry, and processed egg product inspection regulations" and may "not contain material that is regulatory in nature." AR0002872 (emphasis added). Instead of creating new binding rules, Directives only "provide written instructions for employees to effectively carry out their duties in support of the Agency's mission." AR0002860. FSIS Directives thus intentionally are not binding or legally enforceable, and are little more than a reference guide for agency employees. *Accord River Runners*, 593 F.3d at 1072 ("A 'reference source,' of course, is not the same as binding substantive law.").

Because no party, including FSIS, can be brought to task for failing to implement or comply with the Directive, the Directive does not constitute a final agency action subject to judicial review under the APA. It is the underlying provisions of FMIA and its implementing regulations that establish a facility's rights to a grant of inspection, not Directive 6130.1 (or any of the other Directives referenced in the CE decision memoranda). Therefore, Plaintiffs' challenge to the Directive must be dismissed.

B. Issuance Of Directive 6130.1 Did Not Trigger Any Obligations Under NEPA

Even if Directive 6130.1 were subject to judicial review under the APA, it is not an action that would trigger any obligation under NEPA. The Directive is not the "legally relevant cause" of any effect on the environment, as it must be to

trigger review under NEPA. *See Public Citizen*, 541 U.S. at 770. Plaintiffs' claim is that horse slaughter operations cause environmental harm. *See, e.g.*, Pls.' Br. at 8-10. But the Directive does not authorize the slaughter of horses or the operation of any horse slaughter facility. Under FMIA and its implementing regulations, slaughter operations are authorized only by grants of inspection. And, even in the absence of the Directive, FSIS would be legally obligated to issue and implement grants of inspections for facilities that met the requirements of FMIA. *See, e.g.*, 21 U.S.C. §603(a) (mandating that FSIS "shall" cause inspections). Because the Directive was not a legal prerequisite to the grants of inspection, the Directive does not rise even to the level of the "but for" cause of any slaughter operations that the Supreme Court in *Public Citizen* found was inadequate to establish a NEPA obligation. 541 U.S. at 767 ("[A] 'but for' causal relationship is insufficient to make an agency responsible for a particular effect under NEPA and the relevant regulations.").

Plaintiffs contend that the Directive is the legally relevant cause of the alleged environmental harm from horse slaughter operations pursuant to *Public Citizen* because FSIS has the ability to "countermand" that harm by "testing for all substances regularly administered to horses or adopting a passport system like the

one required in Europe." Pls. Br. at 29.[9] This argument misconstrues *Public Citizen*. In *Public Citizen*, the Supreme Court held that "FMCSA has no ability to countermand the President's lifting of the moratorium or otherwise categorically to exclude Mexican motor carriers from operating within the United States," because "FMCSA remains subject to the mandate" of the agency's governing statute that it "shall" authorize motor carriers that meet the requirements of that statute. 541 U.S. at 766. As a result, "[a]ny reduction in emissions that would occur at the hands of FMCSA would be mere happenstance." *Id.* at 773.

Like FMCSA, FSIS has no authority to "countermand" the Congress's lifting of the moratorium on horse slaughter operations, because FSIS is bound by

[9] In addition to being wrong about horse slaughter posing a threat to the environment, as discussed above, Plaintiffs' assertion that testing *all* horses for drug residue will reduce environmental impacts makes little sense. Horses are tested for drug residues *post*-mortem by sending one-pound samples of their tissues to off-site testing facilities. AR0001867. While the testing is taking place, only the edible remains of the animal are held in cold storage pending the result; the blood and offal have already been sent to rendering. Thus, if a test comes back positive, the only effect is that the *edible* portions are then sent to rendering too, instead of into the chain of commerce. Thus, because it is the blood and offal that Plaintiffs contend contaminate the physical environment, there would be no change in that alleged effect as a result of more testing, even if more test resulted in more condemned carcasses. The Supreme Court emphasized in *Metropolitan Edison*, 460 U.S. at 772-73, that the adjective "environmental" implies that "NEPA does not require the agency to assess every impact or effect of its proposed action, but only the impact or effect on the environment," meaning the "physical environment"—"the air, land, and water." Thus, NEPA does not regulate the food safety aspects of FSIS's inspection activities, which is not an effect on the physical environment. In any event, as FSIS has explained, more testing will not result in more positive results.

FMIA's mandate that it "shall" grant inspections to facilities that qualify under FMIA. FMIA limits FSIS's authority in inspecting slaughterhouse facilities to "preventing the use in commerce of meat and meat food products which are adulterated," to "preventing the inhumane slaughtering of livestock," and to preventing mislabeling. 21 U.S.C. §§603(a), (b), 604, 607. Whether the residue testing plan set forth in the Directive mitigates environmental impacts is "mere happenstance," because FSIS may only base that plan and Directive on what FSIS determines to be necessary to ensure that the meats products flowing from the regulated facility are not adulterated.

Any attempt by FSIS to regulate the environmental impacts of slaughter operations through a Directive would be *ultra vires*--beyond the scope of the agency's authority. Again, the decision of the Supreme Court in *NAHB* that the EPA's grants of permitting authority to States did not trigger ESA requirements turned on the fact that the Clean Water Act expressly limited the agency's discretion to considering certain enumerated factors in making those grants, just as FMIA limits FSIS's discretion here. "While the EPA may exercise some judgment in determining whether a State has demonstrated that it has the authority to carry out §402(b)'s enumerated statutory criteria, the statute clearly does not grant it the discretion to add another entirely separate prerequisite [protection of endangered species] to that list." 551 U.S. at 671. Under the principals set forth in *Public*

Citizen and *NAHB*, FSIS cannot add environmental considerations to its mandate to ensure that animals are humanely slaughtered and that meat products are not adulterated or misbranded. Therefore, NEPA does not apply to the directive.

It is also well-settled that NEPA applies only when "an agency action constitutes an 'irreversible and irretrievable commitment of resources,' which exists only where the government surrenders its 'absolute right' to prevent the use of those resources." *Friends of Se's*, 153 F.3d at 1064 (quoting *Conner*, 848 F.2d at 1449); *see also Pit River Tribe v. U.S. Forest Serv.*, 469 F.3d 768, 782 (9th Cir. 2006) ("[A]n EIS is not required in cases where the government has not irretrievably committed resources."). In *Conner*, for instance, the Ninth Circuit held that the Forest Service did not have a NEPA obligation in selling certain gas and oil leases that "make no commitment of any part of the national forests to surface-disturbing activities by the lessees because the government retains *absolute* authority to decide whether any such activities will ever take place on the leased lands." *Conner*, 848 F.2d at 1447 (emphasis in original). Similarly, in *Friends of Southeast's Future*, the Ninth Circuit held that the agency did not irretrievably commit forest resources in issuing a non-binding timber harvest plan, where the agency retained the authority to change the amount of timber ultimately harvested.

153 F.3d at 1063.[10] In *Northcoast Environmental Center v. Glickman*, 136 F.3d 660, 670 (9th Cir. 1998), the Ninth Circuit held that federal agency Management Guidelines establishing, among other things, management objectives and implementation strategies to minimize the spread of a tree root fungus did not "significantly affect the quality of the human environment" because the Guidelines merely "set forth guidelines and goals" and did not "create activities which impact the physical environment," "propose any site-specific activity," or "call for specific actions directly impacting the physical environment."

Here, FSIS did not make any "irreversible and irretrievable" commitment of resources in issuing the Directive. As discussed above, the Directive is non-binding internal agency guidance, is not legally enforceable, and does not authorize any grant of inspection or allow anyone to take actions with environmental impacts. FSIS remains free to unilaterally modify or cancel the Directive at any time, with no obligation to any third party. Thus, by issuing the Directive, FSIS

[10] *See also WildWest Inst. v. Bull*, 547 F.3d 1162, 1169 (9th Cir. 2008) (holding that "the Forest Service's pre-marking of trees did not irretrievably commit it to a particular course of action" in violation of NEPA, even though it spent $208,000 dollars to mark the trees, because "[a]lthough the Forest Service undertook preparatory actions in favor of logging, it clearly retained the authority to change course or to alter the plan it was considering implementing"); *accord Piedmont Environmental Council v. FERC*, 558 F.3d 304, 317 (4th Cir. 2009) (holding that federal agency "was not required to prepare an EA or an EIS in connection with its issuance of the regulations" governing the contents of permit applications for construction of electrical power line corridors because "issuing regulations specifying the content of permit applications is not similar to the action of issuing a permit").

did not surrender its absolute right to deny a grant of inspection to any facility that did not meet the requirements of FMIA, nor did it prevent its inspectors from sampling horses for drug residues at the higher rates advocated by Plaintiffs. For this reason also, Plaintiffs' NEPA challenge to the Directive must fail.

This Court cited 40 C.F.R. §1508.18(b)(2), and *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 73 (2004), to support a conclusion that Directive 6130.1 constitutes "major Federal actions significantly affecting the quality of the human environment" under NEPA. TRO, ECF No. 125 at 3-4. But 40 C.F.R. §1508.18(b)(2) identifies only types of "federal action," and does not contemplate that *all* "formal plans" trigger a NEPA obligation, just as all "specific projects" (*id.* §1508.18(b)(4)) do not trigger NEPA obligations. As discussed above, the Supreme Court, the Tenth Circuit, and other courts have consistently held that NEPA does not apply to agency actions (whether "plans" or "projects") over which the federal agency's discretion is limited or which do not result in an irretrievable and irreversible commitment of resources, among other reasons.

Thus, even assuming the Directive constitutes a "formal plan," it is worlds apart from the Bureau of Land Management ("BLM") land use plan at issue in *Norton*. As the Supreme Court in *Norton* discussed, BLM land use plans are "adopted after notice and comment," "guide and *control* future management actions," and "describe[], for a particular area, allowable uses, goals for future

condition of the land, and specific next steps." 542 U.S. at 59 (citations omitted; emphasis added). Once adopted, BLM must shall "manage the public lands . . . in accordance with the land use plans," *id.* at 59-60 (quoting 43 U.S.C. §1732(a)), and "[a]ll future resource management authorizations and actions . . . *shall conform to the approved plan*." *Id.* at 67 (quoting 43 CFR §1610.5-3(a) (2003), emphasis added). The Supreme Court concluded that "[t]he statutory directive that BLM manage 'in accordance with' land use plans, and the regulatory requirement that authorizations and actions 'conform to' those plans, prevent BLM from taking actions inconsistent with the provisions of a land use plan. Unless and until the plan is amended, such actions can be set aside as contrary to law pursuant to [the APA]." *Id.* at 69. Because BLM land use plans are binding legal documents that are promulgated through notice and comment, and dictate future site-specific projects affecting natural resources across millions of acres of public lands, it is not surprising that (by regulation) their adoption--as well as their amendment and revision--triggers NEPA compliance. *Id.* at 73.

In sharp contrast to BLM land use plans, the FSIS Directive is an internal agency guidance document that is neither binding on the agency nor binding on any future actions the agency takes. *See also* Exhibit C hereto, FSIS Directive 1232.4 at 7 ("FSIS makes inspection-related directives available to regulated industry, but these directives are not regulations and do not carry the force of

law."). Indeed, rather than establish legal requirements as BLM land use plans do, the Directive is essentially a compendium of existing statutory and regulatory requirements, and its consideration in a grant of inspection decision document cannot convert that grant from a non-discretionary action to a discretionary action subject to NEPA requirements.

IV. PLAINTIFFS ARE NOT ENTITLED TO THE RELIEF THEY REQUEST

As discussed above, FSIS complied with NEPA both in issuing the challenged grants of inspection and Directive 6130.1. If, however, the Court finds otherwise, some principles are instructive in determining the appropriate remedy. The law and facts counsel that Directive 6130.1 and the grants of inspection should remain in place pending FSIS's remediation of any deficiency found in its NEPA analyses.

First, remedies must be narrowly tailored to any alleged harm. *See ClearOne Comm's, Inc. v. Bowers*, 643 F.3d 735, 752 (10th Cir. 2011) ("It is well settled that an injunction must be narrowly tailored to remedy the harm shown.") (internal citation omitted). An injunction, if issued, should not be overly broad:

> When a court has found that a party is in violation of NEPA, the remedy should be shaped so as to fulfill the objectives of the statute as closely as possible, consistent with the broader public interest. . . . The court should tailor its relief to fit each particular case, balancing the environmental concerns of NEPA against the larger interests of society that might be adversely affected by an overly broad injunction.

Envtl. Def. Fund v. Marsh, 651 F.2d 983, 1005-06 (5th Cir. 1981).

Second, if there is harmless error, no remedy is needed. *See e.g., N. Cheyenne Tribe v. Norton*, 503 F.3d 836, 842 (9th Cir. 2007); 5 U.S.C. § 706 (due account shall be taken of the rule of prejudicial error). Third, the Supreme Court has instructed that injunctions may not issue as a matter of course. *See, e.g.*, *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542 (1987); *see also N. Cheyenne Tribe*, 503 F.3d at 842 ("We are bound by precedent to hold that a NEPA violation is subject to traditional standards in equity for injunctive relief and does not require an automatic blanket injunction against all development."). Courts must consider traditional principles of equity in issuing injunctions, and Plaintiffs must show that irreparable injury is "likely," as opposed to merely "possible." *Winter v. Natural Res. Defense Council*, 129 S. Ct. 365, 375 (2008).

If this Court finds that FSIS violated NEPA in issuing Directive 6130.1, then the proper remedy is to remand the NEPA analysis to FSIS for additional analysis without vacating the Directive itself. When a court finds an agency's action is arbitrary and capricious, the proper course is to remand to the agency for clarification of the reasons for its decision. *Gonzales v. Thomas*, 547 U.S. 183 (2006) (holding that a court's failure to remand to the agency for further clarification "erroneously deprived the Agency of its usual administrative avenue for explaining and reconciling" the rationale for its decision). Where, as here, "an

agency may be able readily to cure a defect in its explanation of a decision," *see Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009), and no significant harm would result from keeping the agency's decision in place, courts commonly remand without vacating the agency's decision. *See, e.g.*, *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 993 (9th Cir. 2012) (remanding agency rulemaking without vacatur); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) (same); *W. Oil & Gas Ass'n v. EPA*, 633 F.2d 803, 813 (9th Cir. 1980) (same).

In this case, leaving the Directive in place pending completion of any additional NEPA analysis on remand is appropriate. FSIS has already invoked a CE for the Directive. AR0004871. The only action that could remain for FSIS would be to provide a more detailed explanation of its decision to invoke the CE. *See Gonzales*, 547 U.S. at 183. If the Court finds a NEPA violation, it should remand the Directive to FSIS for further explanation.

In this case, the public interest weighs heavily against vacating the Directive during a remand. As noted above, FMIA requires FSIS to issue grants of inspection to qualifying facilities. This statutory mandate holds whether or not FSIS has a Directive in place. The Directive useful guidance to inspectors for conducting those inspections. The case law makes clear that courts should be reluctant to impose equitable relief that will impede the orderly administration of a

governmental responsibility intended to serve the public interest. *Yakus v. United States*, 321 U.S. 414, 440 (1944); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982) (holding that when injunctive relief would harm the public interest, the Court may withhold the relief, even if doing so would burden the movant); *Piedmont Heights Civic Club, Inc. v. Moreland*, 637 F.2d 430, 439 (11th Cir. 1981) (refusing to enjoin highway construction for alleged noncompliance with environmental laws when plaintiff's harm was outweighed by harm caused to the public by traffic and safety hazards on overcrowded highways); *Nat'l Org. for the Reform of Marijuana Laws v. U.S. Dep't of State*, 452 F. Supp. 1226, 1234 (D.D.C. 1978) (withholding an injunction against a federal program assisting the government of Mexico in eradicating heroin and marijuana production pending compliance with NEPA, noting the impact on criminal laws and foreign policy at issue).

Should the Court find that FSIS was obligated to comply with NEPA in issuing the challenged grants of inspection, and that FSIS improperly invoked a CE in issuing those grants, the proper remedy is also to remand those NEPA decisions for reconsideration while leaving the grants in place. Congress has expressly provided that the FMIA covers equine species, 21 U.S.C. § 601(w), and has mandated FSIS inspections of horse slaughter facilities that qualify under the FMIA. *Id.* § 603-04. Those requirements satisfy the public interest. *See* Fed.

Defs.' Opp'n to Pls.' Mtn. for Prelim. Inj., ECF No. 66 at 38-39. The balance of harms and public interest counsel in favor of allowing the continued operation of the facilities during the short interim while FSIS remedies any NEPA deficiency the Court may find.

CONCLUSION

Plaintiffs' NEPA claims are without merit. NEPA does not apply to FSIS's mandatory grants of inspection under FMIA and, even if it did, FSIS reasonably determined that its grants fell within the Agency's CE in accordance with NEPA. As revocable non-binding internal agency guidance, Directive 6130.1 is not "final agency action" subject to judicial review under the APA and, even if it was, its issuance did not trigger any requirements under NEPA. Federal Defendants respectfully request that the Court dismiss Plaintiffs' claims and grant judgment in favor of Federal Defendants.

Respectfully submitted this 27th day of September, 2013.

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2013, I filed through the United States District Court ECF System the foregoing document to be served by CM/ECF electronic filing on all counsel of record.

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