

Kathryn Brack Morrow
Karen Budd-Falen
BUDD-FALEN LAW OFFICES, LLC
300 East 18th Street
Post Office Box 346
Cheyenne, Wyoming 82003
(307) 632-5105 Telephone
(307) 637-3891 Facsimile
Attorneys for Defendant-Intervenors IEBA, et al.

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO**

FRONT RANGE EQUINE RESCUE,
et al.,

Plaintiffs,

and

STATE OF NEW MEXICO,

Plaintiff-Intervenor,

v.

Civil Action No. 1:13-cv-00639-MCA-
RHS

TOM VILSACK, Secretary, United
States Department of Agriculture, et al.,
Federal Defendants,

**DEFENDANT-INTERVENORS'
CONSOLIDATED BRIEF IN
SUPPORT OF AGENCY ACTION**

and

VALLEY MEAT COMPANY, et al.,
Defendant-Intervenors.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Intervenors Valley Meat Company, LLC, Rains Natural Meats, and Chevaline, LLC are for-profit organizations. Each Defendant-Intervenor certifies that they do not have a parent company, and that there is no publicly held company that has a 10% or greater ownership interest (such as stock or partnership shares) in the organization.

/s/A. Blair Dunn

A. Blair Dunn, Esq.

Responsible Transportation, L.L.C. states that it has no parent corporation nor are there any publicly held corporations owning 10% or more of its stock.

/s/Patrick J. Rogers

Patrick J. Rogers

Patrick J. Rogers, LLC

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendant-Intervenors International Equine Business Association, New Mexico Cattle Growers' Association, South Dakota Stock Growers Association, United Horsemen and Ranchers-Cattlemen Action Legal Fund United Stockgrowers of America are nonprofit, membership associations formed and operated under

relevant state laws. They are neither publicly-owned companies nor are they owned or managed by any parent corporations.

Defendant-Intervenor Kujoyukuri Ltd. is a for-profit organization formed under the laws of Japan. Defendant-Intervenor Kujoyukuri Ltd. certifies that it does not have a parent company, and that there is no publicly held company that has a 10% or greater ownership interest (such as stock or partnership shares) in the organization.

/s/ Kathryn Brack Morrow

Kathryn Brack Morrow

BUDD-FALEN LAW OFFICES, LLC

TABLE OF CONTENTS

CORPORATE DISCLOSURE STATEMENT

STATEMENT OF THE CASE	1
STATEMENT OF FACTS	4
SUMMARY OF THE ARGUMENT	7
LEGAL BACKGROUND	10
I. NATIONAL ENVIRONMENTAL POLICY ACT	10
II. ADMINISTRATIVE PROCEDURE ACT	13
III. FEDERAL MEAT INSPECTION ACT	14
ARGUMENT	18
I. STANDARD OF REVIEW	18
A. Standard of Review for Agency Interpretations of Statute and Regulation	21
II. PLAINTIFFS LACK APPROPRIATE STANDING TO CHALLENGE THE GRANT OF INSPECTION ISSUED TO RESPONSIBLE TRANSPORTATION	23
III. PLAINTIFFS' CLAIM THAT THE FEDERAL DEFENDANTS VIOLATED NEPA BY FAILING TO CONDUCT SUFFICIENT ENVIRONMENTAL REVIEW PRIOR TO ISSUING A "NEW DRUG RESIDUE PROGRAM" IS NOT A COGNIZABLE CLAIM UNDER THE APA	27

A.	Federal Defendants’ “New Drug Residue Program” is Not a Discrete Agency Action Subject to Review Under the APA	21
B.	Federal Defendants’ Directive 6130.1 is Not a Final Agency Action Subject to Review Under the APA	30
C.	Even if Plaintiffs’ Challenge to Directive 6130.1 Represents a Cognizable Claim under the APA, the Requirements of NEPA Remain Inapplicable to the Directive	39
IV.	FEDERAL DEFENDANTS’ ISSUANCE OF GRANTS OF INSPECTION WERE MANDATORY ACTIONS, NOT SUBJECT TO NEPA ANALYSIS	42
V.	EVEN IF FEDERAL DEFENDANTS’ GRANT OF INSPECTION WAS SUBJECT TO NEPA ANALYSIS, CATEGORICAL EXCLUSION WAS PROPERLY APPLIED	48
A.	No Extraordinary Circumstances precluding use of the categorical exclusion were present.	51
VI.	PLAINTIFFS HAVE NOT DEMONSTRATED THAT FSIS IMPROPERLY RELIED UPON POLITICAL CONSIDERATIONS	66
	CONCLUSION	68
	CERTIFICATE OF COMPLIANCE	
	CERTIFICATE OF DIGITAL SUBMISSIONS	
	CERTIFICATE OF SERVICE	

TABLE OF AUTHORITIES

CASES

Alaska Ctr. for the Env’t v. U.S.,
189 F.3d 851, 857 (9th Cir. 2007) 19, 21, 50, 52, 53

Allen v. Wright,
468 U.S. 757, 758 (1984) 26

Amigos Bravos v. U.S. Bureau of Land Mgmt.,
6:09-CV-00037-RB-LFG, 2011 WL 7701433 (D.N.M. Aug. 3, 2011) 11, 12,
53, 54, 58

Andrus v. Sierra Club,
442 U.S. 347, 358 (1979) 11

Att. Gen. of Okla. v. Tyson Foods, Inc.,
565 F.3d 769, 776 (10th Cir. 2009) 34

Back Country Horsemen of Am. v. Johanns,
424 F. Supp.2d 89, 99 (D.D.C. 2006) 50

Bar MK Ranches v. Yeutter,
994 F.2d 735, 738 (10th Cir. 1993) 18, 23

Bennett v. Spear,
520 U.S. 154, 172 (1997) 15, 31, 41

Blue Mountains Biodiversity Project v. Blackwood,
161 F.3d 1208, 1212 (9th Cir.1998) 59

Casias v. Sec’s of Health and Human Servs.,
933 F.2d 799, 800 (10th Cir. 1991) 50

Chevron U.S.A. v Natural Res. Def. Council, Inc.,
 467 U.S. 837, 843–44 (1984) 17, 21, 22, 47

Christensen v. Harris Cnty.,
 529 U.S. 576, 586–87 (2000) 17, 22

Ciba-Geigy Corp. v. U.S.E.P.A.,
 801 F.2d 430, 435–36 (D.C. Cir. 1986) 35

Citizens to Pres. Overton Park v. Volpe,
 401 U.S. 402 (1971) 18

Citizens’ Comm. To Save Our Canyons v. Krueger,
 513 F.3d 1169, 1176 (10th Cir. 2008) 19, 20

Citizens’ Comm. to Save Our Canyons v. U.S. Forest Serv.,
 297 F.3d 1012, 1023 (10th Cir. 2002) 19,20

City of Colo. Springs v. Solis,
 589 F.3d 1121, 1131 (10th Cir. 2009) 19

City of Gillette, Wyoming v. FERC,
 737 F.2d 883, 884–85 (10th Cir. 1984) 23

Ctr. for Legal Advocacy v. Hammons,
 323 F.3d 1262, 1267 (10th Cir. 2003) 22

Ctr. for Native Ecosystems v. Cables,
 509 F.3d 1310, 1329 (10th Cir. 2007) 31

Davis v. Morton,
 469 F.2d 593, 596-97 (10th Cir. 1972) 45

Dep't. of Transp. v. Pub. Citizen,
 541 U.S. 752, 763 (2004) 13

Fla. Power & Light v. Liorior,
 460 U.S. 729, 743-44 (1985) 59

Forest Guardians v. U.S. Fish & Wildlife Serv.,
 611 F.3d 692, 711 (10th Cir. 2010) 11

Found. on Econ. Trends v. Lyng,
 943 F.2d 79, 86 (D.C.Cir. 1991) 28

Friends of the Earth, Inc. v. U.S. Army Corps of Eng'rs,
 109 F. Supp. 2d 30, 40 (D.D.C. 2000) 45

FTC v. Standard Oil of Cal.,
 449 U.S. 232, 239 (1980) 31

Fund for Animals v. Norton,
 281 F. Supp.2d 209, 235 (D.D.C. 2003) 54

Gen. Dynamics Land Sys., Inc. v Cline,
 540 U.S. 581, 600 (2004) 21

Herrera v. Santa Fe Pub. Sch.,
 792 F.Supp.2d 1174, 1179 (D.N.M. 2011) 34

Hillsdale Env'tl. Loss Prevention, Inc. v. U.S. Army Corps of Eng'rs,
 702 F.3d 1156, 1165 (10th Cir. 2012) 20

Humane Society v. Johanns
 520 F. Supp. 2d 8 (D.D.C. 2007) 45-47, 50

Hunt v. Wash. State Apple Adver. Comm’n,
432 U.S. 333, 342 (1997) 24

Impact Energy Res., LLC v. Salazar,
693 F.3d 1239, 1253–54 (10th Cir. 2012) 31

Lujan v. Defenders of Wildlife,
504 U.S. 555, 560 (1992) 25, 26

Lujan v. National Wildlife Federation,
497 U.S. 871 (1990) 27, 28, 30

Macht v. Skinner,
916 F.2d 13 (D.C. Cir. 1990) 45

Native Ecosystems Council v. U.S. Forest Serv.,
428 F.3d 1233, 1240 (9th Cir.2005) 59

Nat’l Ass’n of Home Builders v. Defenders of Wildlife,
551 U.S. 644, 672 (2007) 20, 38, 42

New Mexico ex rel. Richardson v. Bureau of Land Mgmt.,
565 F.3d 683, 703 (10th Cir. 2009) 10, 42, 43

NISH v. Rumsfeld,
188 F.Supp.2d 1321, 1324 (D.N.M. 2002) 21

Olenhouse v. Commodity Credit Corp.,
42 F.3d. 1560, 1580 (10th Cir. 1994) 13, 18, 19

Ore. Natural Desert Ass’n v. U.S. Forest Serv.,
465 F.3d 977, 984 (9th Cir. 2006) 32, 35

Park Cnty. Res. Council, Inc. v. U.S. Dep’t of Agric.,
817 F.2d 609, 620 (10th Cir. 1987) 10

Presidio Golf Club v. Nat’l Park Serv.,
155 F.3d 1153, 1163 (9th Cir. 1998) 62

Ramsey v. Kantor,
96 F.3d 434, 444 (9th Cir. 1996) 44

Rhodes v. Johnson,
153 F.3d 785, 789 (7th Cir. 1998) 21

Robertson v. Methow Valley Citizens Council,
490 U.S. 332, 355-56 (1989) 11, 45

Schweiker v. Hansen,
450 U.S. 785, 789–90 (1981) 33

Sierra Club v. Morton,
405 U.S. 727, 739 (1972) 24

Skidmore v. Swift & Co.,
323 U.S. 134, 140 (1944) 22

Town of Superior v. U.S. Fish & Wildlife Serv.,
913 F. Supp.2d 1087, 1120 (D. Colo. 2012) 54, 59

Utah Env’tl. Cong. v. Bosworth,
443 F.3d 732, 739 (10th Cir. 2006) 20, 21, 51-53, 62

Utah Env’tl. Cong. v. Russell,
518 F.3d 817, 821 (10th Cir. 2008) 12, 13

Utahns for Better Transp. v. U.S. Dep’t. of Transp.,
305 F.3d 1152, 1164 (10th Cir. 2002) 18, 39

W. Ill. Home Health Care, Inc. v. Herman,
150 F.3d 659, 663 (7th Cir. 1998) 35

W. Radio Servs. Co., Inc. v. Espy,
79 F.3d 896, 901 (9th Cir. 1996) 33, 39

Wildearth Guardians v. U.S. Forest Serv.,
668 F. Supp. 2d 1314, 1321 (D.N.M. 2009) 11, 13, 14, 49

Wyoming v. U.S. Dept. of Agric.,
661 F.3d 1209, 1243 (10th Cir. 2011) 42

Wyoming v. U.S.,
279 F.3d 1214, 1238 (10th Cir. 2002) 19

STATUTES

5 U.S.C. §§ 701–706 18, 30

5 U.S.C. § 706 59

5 U.S.C. § 706(2) 14, 19

5 U.S.C. § 706(2)(A) 13, 19

5 U.S.C. §§ 706(2)(A), (D) 13

21 U.S.C. § 601 et. seq. 2, 14

21 U.S.C. § 601(w) 2

21 U.S.C. §§ 602–605	17, 38
21 U.S.C. § 603	2
21 U.S.C. § 603(a)	2, 29
21 U.S.C. § 603(b)	15
21 U.S.C. § 604	2, 15
21 U.S.C. § 671	15
42 U.S.C. § 4332(C)	10, 12
72 Stat. 862; 7 U.S.C. 1901–1906	15
FY20212 Appropriations Act, Pub. L. 112-55, 125 Stat. 562 (Nov. 18, 2011)	3
Pub. L. 109-97, § 794, 119 Stat. 2164 (A.R. 51) (Nov. 10, 2005)	3

RULES AND REGULATIONS

7 C.F.R. § 1b.3(c)	49
7 C.F.R. § 1b.4	50, 51
7 C.F.R. § 1b.4(b)(6)	49
9 C.F.R §§ 300.1 and 300.2	16
9 C.F.R. Parts 302, 304, 307, 416, and 417	16, 47
9 C.F.R. § 304.1(a)	16

9 C.F.R § 304.2(b)	17
9 C.F.R. §§ 304.1–304.3	38
9 C.F.R. §§ 304.3(b) and 500.7(a)(1)–(5)	38
9 C.F.R. §§ 304.2-304.3 and 500.7	40
9 C.F.R. § 500.7	17, 41
40 C.F.R. §§ 1502.13, 1502.14(a)	42
40 C.F.R. § 1504.1(c)	12
40 C.F.R. § 1507.3(b)(2)	12
40 C.F.R. § 1508.4	12, 49, 51
40 C.F.R. § 1508.27	11, 53
40 C.F.R. § 1508.27(b)	12, 54
40 C.F.R. § 1508.27(b)(2), (5)	56, 58
40 C.F.R. § 1508.27(b)(4)	58
40 C.F.R. § 1508.27(b)(6)	61
40 C.F.R. § 1508.27(b)(9)	64
40 C.F.R. § 1508.27(10)	63

OTHER AUTHORITIES

64 Fed. Reg. 66541–66542 (Nov. 29, 1999) 17, 41

Tadlock Cowan, Cong. Res. Serv. Rs21842, Horse Slaughter Prevention Bills and Issues 1 (2012) 2

STATEMENT OF THE ISSUES

The issues before this Court for review are discrete, legal issues, and are limited to the following:

1. Whether the Plaintiffs have properly alleged that they have standing to challenge the grant of inspection to the Responsible Transportation facility in Sigourney, Iowa?
2. Whether a new drug residue program is a discrete, final agency action which is subject to NEPA analysis and documentation?
3. Whether a FSIS grant of inspection is subject to NEPA analysis and documentation, and if so, whether it is properly subject to the FSIS categorical exclusion?

STATEMENT OF THE CASE

The United States Department of Agriculture – Food Safety Inspection Service (“FSIS”) is an agency with a limited, narrowly focused mission: to provide an inspection service in order to prevent meat and meat products which are adulterated from entering into the stream of commerce. Through this action, Plaintiffs seek to burden this agency with time-consuming, resource-demanding

procedural requirements, the application of which is contrary to the non-discretionary duties that FSIS is charged with implementing.

Safe and humane equine processing has occurred in the United States for many years. See Tadlock Cowan, Cong. Res. Serv. Rs21842, Horse Slaughter Prevention Bills and Issues 1 (2012). Ensuring that equine processing, like all meat processing, is conducted in a safe and humane manner requires a rigorous regulatory effort and an adequate inspection service. In accordance with the Federal Meat Inspection Act (“FMIA”), 21 U.S.C. § 601 et. seq., and for “the purpose of preventing the use in commerce of meat and meat products which are adulterated” the “Secretary shall cause to be made, by inspectors appointed for that purpose,” an ante-mortem “examination and inspection of *all* amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment,” 21 U.S.C. § 603(a), and a post-mortem examination of all carcasses and parts of all amenable species. 21 U.S.C. § 604. “Amenable species” includes all cattle, sheep, swine, goats, horses, mules, and other equines. See 21 U.S.C. §§ 601(w), 603.

Despite tradition and statutory authority, equine processing was temporarily halted from 2007-2012 with a provision withholding funds for the inspection of

equine processing facilities included in the annual Agricultural Appropriations bill. See Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006, Pub. L. 109-97, § 794, 119 Stat. 2164 (A.R. 51) (Nov. 10, 2005) (annually reinstated until 2012).

Recently, however, members of Congress responded to public and industry support by approving an amendment to the FY2012 Appropriations Act that lifted the ban on funds for the inspection of equine animal processing facilities. See FY2012 Appropriations Act, Pub. L. 112-55, 125 Stat. 562 (Nov. 18, 2011). Accordingly, equine processing facilities were once again treated as all other animal processing facilities. On June 28, 2013, FSIS granted Valley Meat Company, LLC a grant of inspection. See AR 2457-2465. On July 2, 2013, FSIS granted Responsible Transportation, LLC a grant of inspection, as well. See AR 3274-3280.¹

¹ On September 13, 2013, FSIS officials officially completed review of Rains Natural Meats' application for inspection services for equine processing. Despite the completion of the categorical exclusion review and approval of the application, FSIS officials have not officially issued the grant of inspection. Thus, Plaintiffs and Plaintiff-Intervenor have not officially challenged an agency action granting inspection service to Rains Natural Meats. However, all indications suggest a challenge will be initiated upon issuance of the grant. See Document No. 156

Despite its thorough review and lack of discretion, Plaintiffs have determined that these two grants of inspection are cause for a full-fledged donnybrook, challenging the two grants of inspection as improperly granted. Plaintiffs seek an order requiring FSIS to engage in analysis and documentation pursuant to the National Environmental Policy Act (“NEPA”) for both the grants of inspection, as well as what Plaintiffs allege is FSIS’ “drug residue testing plan.” In addition, Plaintiffs seek an order enjoining inspections at the Valley Meat, Responsible Transportation, and Rains Natural Meats facilities until FSIS completes an environmental analysis under NEPA. Such NEPA analysis is not required, and is not warranted in these particular instances.

STATEMENT OF FACTS

Valley Meat Company, LLC (“Valley Meat”) is a small cattle slaughter and processing facility in Roswell, New Mexico. The company has conducted federally inspected commercial slaughter of cattle, veal calves, goats, sheep, lambs and swine since January 1991. See AR 2467. Valley Meat is located 12 miles

(requesting that this Court enjoin federal defendants from conducting inspections at the Rains Natural Meats facility). Therefore, the arguments section of Defendant-Intervenors’ consolidated brief will appropriately address FSIS decisionmaking and documentation concerning the Rains Natural Meats facility.

from the nearest municipality, and relies on septic tanks and lagoons for waste water disposal, rather than Roswell's waste water disposal system. See AR 2476 n.

6. On March 2, 2012, Valley Meat filed an application with the United States Department of Agriculture, Food Safety and Inspection Service ("FSIS") to modify its grant of inspection to receive inspection services for the commercial processing of horses, mules, and other equines. See AR 2467.

Similarly, Responsible Transportation, LLC ("Responsible Transportation") was organized in 2010 by local investors in Iowa to own and operate an equine slaughter and processing plant in Sigourney, Iowa. See AR 3282. Responsible Transportation filed an application for a grant of inspection to receive inspection services for the commercial processing of horses, mules, and other equines on December 13, 2012. See id.

Rains Natural Meats ("Rains") is a small meat and poultry slaughtering facility in Gallatin, Missouri. See AR4868. The facility was constructed on a five-acre site in 1998 and received its first grant of inspection that same year. See id. On January 15, 2013, Rains submitted an application for a grant of inspection to receive inspection services for the commercial processing of horses, mules, and other equines. See id.

Following the completion of all appropriate application materials and the fulfillment of all necessary regulatory requirements, Valley Meat and Responsible Transportation were finally issued their grants of inspection earlier this year. See AR 2457-2465 (Grant of Inspection to Valley Meat, issued June 28, 2013); see also AR 3274-3280 (Grant of Inspection to Responsible Transportation, issued July 2, 2013). Rains' application for inspection services was recently approved, but the facility has not been issued a grant of inspection. See AR4868-4878 (Categorical Exclusion Decision Memo for Rains, completed September 13, 2013). However, due to the present litigation, inspection never occurred at any of the facilities.

Defendant-Intervenors comprise the three facilities discussed above, Valley Meat, Responsible Transportation, and Rains, which have a direct interest in the outcome of this litigation. Defendant-Intervenors are also made up of other facilities which hope to acquire grants of inspection for equine processing; business organizations which support the horse processing industry; potential purchasers of the products which Valley Meat, Responsible Transportation, and Rains hope to produce; as well as ranchers and other individuals who have an interest in a regulated, humane disposal method for unwanted horses. Further,

Defendant-Intervenors also include the Yakima Nation, who has suffered harm as a result of unwanted horses on their reservation.

SUMMARY OF THE ARGUMENT

Plaintiffs allege that FSIS impermissibly issued grants of inspection to Valley Meat and to Responsible Transportation, and seek an order setting aside those grants of inspection, requiring the FSIS to engage in NEPA analysis prior to issuing grants of inspection or implementing their “drug residue testing plan.” However, NEPA is not applicable either to the grants of inspection, or to anything that comprises the alleged “drug residue testing plan.”

First, Defendant-Intervenors challenge Plaintiffs’ standing with regard to their claims related to the Responsible Transportation facility in Sigourney, Iowa. Plaintiffs have failed to demonstrate that any of their members would have the standing to individually sue to challenge Responsible Transportation’s grant of inspection. Therefore, they have not demonstrated organizational standing.

Should Plaintiffs have standing to pursue their claims, Plaintiffs’ attempt to challenge a “new drug residue program” does not constitute a cognizable claim pursuant to the Administrative Procedure Act (“APA”). First, Plaintiffs failed to challenge a “discrete agency” action. Instead of pointing to one particular action,

Plaintiffs attempt to remedy perceived flaws with an entire administrative program. Such broad based challenges to programmatic functions of an agency, particularly day-to-day activities, have been explicitly and directly rejected by the United States Supreme Court.

Presuming that Plaintiffs' challenge is directed at FSIS Directive 6130.1 ("the Directive"), as it *now* appears, Plaintiffs' effort again fails. The APA provides review only for actions made reviewable by a relevant statute or *final* agency action for which there is no other adequate remedy in court. Here, the Directive bears none of the necessary hallmarks of a final agency action. As a threshold matter, the Directive's own language belies any claim that it marks the consummation of the agency's decisionmaking process. Further, a pragmatic review of the Directive reveals that it neither determines rights and obligations nor causes legal consequences to flow from it.

Ultimately, even assuming Plaintiffs' challenge to the Directive constituted a final agency action, it remains that the Directive is not the legally relevant cause of any effect on the environment, as is necessary to trigger review under NEPA. Practically, the Directive is nothing more than an internal instruction document. In

purely legal terms, FSIS's limited discretion to issue or deny a grant of inspection cannot be enlarged by an examination of the Directive's sufficiency.

Plaintiffs also argue that FSIS' decisions to issue grants of inspection to Valley Meat and Responsible Transportation are major Federal actions subject to NEPA review. This is simply antithetical to the purpose of the NEPA statute, as the issuance of grants of inspection is a mandatory act which FSIS is required to perform should a facility meet the necessary requirements. As FSIS is afforded no discretion in whether or not to issue the grants of inspection, it could not meaningfully engage in the alternatives analysis that is the "heart" of the NEPA process.

However, should this Court determine that NEPA is applicable to the decision to issue grants of inspection, it should also find that FSIS met its NEPA requirements through the valid use of a categorical exclusion. FSIS thoroughly analyzed and applied all of the relevant factors to determine not only that a categorical exclusion was appropriate, but also that no extraordinary circumstances were implicated which would preclude the application of the categorical exclusion. In this matter, neither the Plaintiffs nor a very extensive administrative record

provide any reason to doubt FSIS' conclusion that none of the possible effects from the grant of inspection are potentially significant.

LEGAL BACKGROUND

I. NATIONAL ENVIRONMENTAL POLICY ACT

The National Environmental Policy Act ("NEPA") applies to "major Federal actions significantly affecting the quality of the human environment." 42 U.S.C. § 4332(C). "NEPA requires federal agencies to pause before committing resources to a project and consider the likely environmental impacts of the preferred course of action as well as reasonable alternatives." New Mexico ex rel. Richardson v. Bureau of Land Mgmt., 565 F.3d 683, 703 (10th Cir. 2009). The Tenth Circuit has recognized that, "although labeled an 'environmental' statute, NEPA is in essence a *procedural* statute; it does not require agencies to elevate environmental concerns over other appropriate considerations." Park Cnty. Res. Council, Inc. v. U.S. Dep't of Agric., 817 F.2d 609, 620 (10th Cir. 1987) (emphasis in original).

"The requirements of the statute have been augmented by longstanding regulations issued by the Council on Environmental Quality ("CEQ"), to which [this Court] owe[s] substantial deference." New Mexico ex rel. Richardson, 565 F.3d at 703. The statutory requirements and implementing regulations meet

NEPA's "twin aims. First, [NEPA] places upon an agency the obligation to consider every significant aspect of the environmental impact of a proposed action. Second, it ensures that the agency will inform the public that it has indeed considered environmental concerns in its decisionmaking process." Forest Guardians v. U.S. Fish & Wildlife Serv., 611 F.3d 692, 711 (10th Cir. 2010).

These regulations are entitled to substantial deference. See Wildearth Guardians v. U.S. Forest Serv., 668 F. Supp. 2d 1314, 1321 (D.N.M. 2009), citing Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 355-56 (1989); Andrus v. Sierra Club, 442 U.S. 347, 358 (1979).

Pursuant to 40 C.F.R. § 1508.18, a "major Federal action" includes "actions with effects that may be major and which are potentially subject to Federal control and responsibility. Major reinforces but does not have a meaning independent of significantly (§1508.27)." Accordingly, actions are deemed "major" if they "significantly" affect the environment as defined pursuant to 40 C.F.R. § 1508.27. Whether an action "significantly" affects the environment involves considerations of both "context" and "intensity." See id.; see also Amigos Bravos v. U.S. Bureau of Land Mgmt., 6:09-CV-00037-RB-LFG, 2011 WL 7701433 (D.N.M. Aug. 3, 2011). A consideration of context "means that the significance of an action must

be analyzed in several contexts such as society as a whole (human, national), the affected region, the affected interests, and the locality.” See id. at § 1508.27(a).

An evaluation of “intensity,” which refers to “the severity of the impact,” includes an assessment of several factors listed in 40 C.F.R. § 1508.27(b).

Although NEPA requires federal agencies to prepare an environmental impact statement (“EIS”), or a less detailed environmental assessment (“EA”) for major federal actions significantly affecting the quality of the human environment, see 42 U.S.C. § 4332(c) and 40 C.F.R. § 1504.1(c), federal agencies may identify classes of actions that normally do not have a significant effect on the human environment, either individually or cumulatively. See 40 C.F.R. § 1507.3(b)(2). These classes of actions, which have no effect on the human environment either individually or cumulatively, are considered to be “categorically excluded” from NEPA requirements. See 40 C.F.R. § 1508.4; see also Utah Env'tl. Cong. v. Russell, 518 F.3d 817, 821 (10th Cir. 2008). Despite allowing federal agencies to identify classes of action that are categorically excluded from NEPA requirements, NEPA still requires an agency to determine and inform the agency decision maker on whether or not there are any potential environmental impacts that may result from a proposed action of that agency. 40 C.F.R. § 1508.4. Thus, an agency must

determine that extraordinary circumstances do not exist before relying upon a categorical exclusion in a particular instance. See Utah Envtl. Cong. v. Russell, 518 F.3d at 821.

II. ADMINISTRATIVE PROCEDURE ACT

Because NEPA provides no private right of action, Plaintiffs' claims have been brought pursuant to the Administrative Procedure Act ("APA"). See 5 U.S.C. § 706(2)(A); see also Dep't. of Transp. v. Pub. Citizen, 541 U.S. 752, 763 (2004); Olenhouse v. Commodity Credit Corp., 42 F.3d. 1560, 1580 (10th Cir. 1994); WildEarth Guardians v. U.S. Forest Serv., 668 F. Supp. 2d 1314, 1324 (D.N.M. 2009).

Under the APA, this Court shall "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law [or] without observance of procedure required by law." 5 U.S.C. §§ 706(2)(A), (D). The Tenth Circuit has explained: "the essential function of judicial review is a determination of (1) whether the agency acted within the scope of its authority, (2) whether the agency complied with prescribed procedures, and (3) whether the action is otherwise arbitrary, capricious or an abuse of discretion." Olenhouse, 42 F.3d at 1574.

In conducting judicial review pursuant to the APA, this Court “reviews the entire administrative record or so much of that record as has been provided by the parties.” *WildEarth Guardians*, 668 F. Supp. 2d at 1325; see 5 U.S.C. § 706(2).

III. FEDERAL MEAT INSPECTION ACT

The Federal Meat Inspection Act (“FMIA”), 21 U.S.C. §§ 601 et seq., is the cornerstone statute outlining the USDA’s ongoing effort to ensure that any meat processed and distributed domestically, or imported, is safe, wholesome, and unadulterated. Accordingly, and “for the purpose of preventing the use in commerce of meat and meat food products which are adulterated,” Congress authorized an unambiguous demand that

the Secretary [of Agriculture] shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all cattle, sheep, swine, goats, horses, mules, and other equines before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce.

21 U.S.C. § 603(a) (emphasis added). Additionally, and to effectuate the same purpose, Congress demanded that the “Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of

the carcasses and parts thereof of all cattle, sheep, swine, goats, horses, mules, and other equines to be prepared . . . as articles of commerce which are capable of use as human foods.” Id. § 604 (emphasis added).

In both instances, congressional intent – that any facility, whether slaughtering, packing, meat-canning, rendering, or similar, that processes meat shall have inspectors – is set forth plainly with clear, non-discretionary language. The statute’s *only* references to Secretarial authority to deny, withhold, or withdraw inspection are based on limited circumstances and findings: that a facility slaughtered or handled livestock not in accordance with the humane methods outlined in the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901–1906), 21 U.S.C. § 603(b); that a facility failed to destroy condemned carcasses, parts, meat or meat food products, 21 U.S.C. § 604; that a facility failed to maintain sanitary conditions; or, that an applicant or recipient is unfit because of criminal convictions related to “acquiring, handling, or distributing of unwholesome, mislabeled, or deceptively packaged food,” 21 U.S.C. § 671. However, these limited circumstances and findings represent discretion on substantive determinations and have no bearing on the procedures of decisionmaking. See Bennett v. Spear, 520 U.S. 154, 172 (1997) (“[i]t is

rudimentary administrative law that discretion as to the substance of the ultimate decision does not confer discretion to ignore the required procedures of decisionmaking.”). Thus, the limited discretion of the FMIA leaves the agency with no real discretion to affect the outcome of the action.

The standards and requirements of the FMIA are implemented by numerous regulations. See, e.g., 9 C.F.R. Parts 302, 304, 307, 416, and 417. Under the regulations, FSIS is granted authority by the Secretary to implement the inspection system and to ensure the purposes of the statute are enforced. See 9 C.F.R §§ 300.1 and 300.2. FSIS effectuates the purposes of the FMIA by requiring all entities necessitating inspection personnel to apply for a grant of inspection. See 9 C.F.R. § 304.1(a). The regulations provide the FSIS Administrator proper authority to grant inspection upon his determination that the applicant and the establishment are eligible or refuse to grant inspection at any establishment if

he determines that it does not meet the requirements of this part or the regulations in parts 305, 307, and part 416, §§ 416.1 through 416.6 of this chapter or that the applicant has not received approval of labeling and containers to be used at the establishment as required by the regulations in parts 316 and 317. Any application for inspection may be refused in accordance with the rules of practice in part 500 of this chapter.

See, e.g., 9 C.F.R § 304.2(b) (emphasis added).

Sections 304.2 and 500.7 of the regulations enumerate the exhaustive list of substantive determinations that provide grounds to refuse or deny a grant of inspection. See 9 C.F.R. § 500.7. The list documents the agency’s thorough review, interpretation, and determination of what must happen before an applicant’s grant of inspection may be refused or denied. See 64 Fed. Reg. 66541 (Nov. 29, 1999) (publication of the agency’s final rule concerning enforcement authority and procedures). Because the rules (and the list) represent the agency’s interpretation of the FMIA and because they went through notice and comment, then they should be accorded Chevron deference. See Chevron U.S.A. v Natural Res. Def. Council, Inc., 467 U.S. 837, 843–44 (1984); see also Christensen v. Harris Cnty., 529 U.S. 576, 586–87 (2000).

Ultimately, the agency’s interpretation of the statute ensures compliance with Congress’ express intent to guarantee that meat and poultry products are “wholesome, not adulterated, and entitled to bear the legend ‘inspected and passed.’” See 64 Fed. Reg. 66541–66542; see also FMIA, 21 U.S.C. §§ 602–605. In turn, the agency properly interprets the statute and regulations as imparting only ministerial responsibilities to validate that meat is safe. See AR3284 and AR2469

(noting that “a grant of inspection under the FMIA is purely ministerial”). The agency’s interpretation of its own regulation is also accorded great deference. See Bar MK Ranches v. Yeutter, 994 F.2d 735, 738 (10th Cir. 1993).

ARGUMENT

I. STANDARD OF REVIEW

When determining whether the FSIS acted lawfully when it relied on FMIA and FSIS regulations to issue modified inspection instructions for equine processing facility inspectors and when it issued grants of inspection to qualified equine processing facilities, the proper standard of review is set forth in the APA. See 5 U.S.C. §§ 701–706. Both the Tenth Circuit and the United States Supreme Court have examined the scope of judicial review under the APA. See Olenhouse, 42 F.3d. at 1580; Citizens to Pres. Overton Park v. Volpe, 401 U.S. 402 (1971). The ultimate resolution of Plaintiffs’ claims will also require judicial review of FSIS’s interpretation and application of FMIA and FSIS regulations.

Because NEPA does not provide for an independent standard of review, the APA governs this Court’s review of the Plaintiffs’ claims. See Utahns for Better Transp. v. U.S. Dep’t. of Transp., 305 F.3d 1152, 1164 (10th Cir. 2002). Pursuant to the APA, a reviewing court must affirm an agency action, unless it is “arbitrary,

capricious, an abuse of discretion, or otherwise not in accordance with the law.” 5 U.S.C. § 706(2)(A); see also Citizens’ Comm. to Save Our Canyons v. U.S. Forest Serv., 297 F.3d 1012, 1023 (10th Cir. 2002) (citing Alaska Ctr. for the Env’t v. U.S., 189 F.3d 851, 857 (9th Cir. 2007)). Review of an action under the arbitrary and capricious standard is undertaken upon an examination of the entire administrative record or those portions presented and cited by the parties. See 5 U.S.C. § 706(2).

“A presumption of validity attaches to the agency action and the burden of proof rests with the appellants who challenge such action.” Citizens’ Comm. To Save Our Canyons v. Krueger, 513 F.3d 1169, 1176 (10th Cir. 2008) (internal quotations and citation omitted). The standard of review directs the district court “to engage in a substantive review to determine if the agency considered relevant factors and articulated a reasonable basis for its conclusions.” Olenhouse, 42 F.3d at 1580. To fulfill its function, the reviewing court must complete a “thorough, probing, in depth review.” Wyoming v. U.S., 279 F.3d 1214, 1238 (10th Cir. 2002) (internal quotations and citation omitted).

However, the court’s standard of review remains narrow, and the court “is not empowered to substitute its own judgment for that of the agency.” City of

Colo. Springs v. Solis, 589 F.3d 1121, 1131 (10th Cir. 2009) (internal quotations and citation omitted). A court will “uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned.” Nat’l Ass’n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658 (2007) (internal quotation and citation omitted). Indeed, the “standard of review is very deferential to the agency.” Hillsdale Envtl. Loss Prevention, Inc. v. U.S. Army Corps of Eng’rs, 702 F.3d 1156, 1165 (10th Cir. 2012) (internal quotation and citation omitted). The deference afforded agency decisions “is especially strong where the challenged decisions involve technical or scientific matters within the agency’s area of expertise.” Utah Envtl. Cong. v. Bosworth, 443 F.3d 732, 739 (10th Cir. 2006). When the review requires a look at the agency’s factual determinations as part of its NEPA process, short of a “clear error of judgment,” the court asks only whether the agency took a “hard look” at the information relevant to the decision. See Citizens’ Comm. to Save Our Canyons v. Krueger, 513 F.3d at 1178.

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. See Citizens’ Comm. to Save Our Canyons v. U.S. Forest Serv., 297 F.3d 1012, 1023

(10th Cir. 2002), citing Alaska Ctr. for the Env't v. U.S., 189 F.3d 851, 857 (9th Cir. 1999); see also Sierra Club v. Bosworth, 510 F.3d 1016, 1022-23 (9th Cir. 2007). When reviewing an agency's interpretation and application of its categorical exclusions under the arbitrary and capricious standard, courts are deferential. See id., citing Alaska Ctr. for the Env't, 189 F.3d at 857; and Rhodes v. Johnson, 153 F.3d 785, 789 (7th Cir. 1998).

A. Standard of Review for Agency Interpretations of Statute and Regulation

When reviewing an agency action under the APA, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the agency given the responsibility and authority to administer and give effect to the statute. See NISH v. Rumsfeld, 188 F.Supp.2d 1321, 1324 (D.N.M. 2002)(citing Chevron, 467 U.S. at 844). Based on Chevron, a court determines the degree of deference afforded to an agency's interpretation using a multi-step approach. See id. at 842. The court first looks to statutory text, history and purpose to determine "whether Congress has directly spoken to the precise question at issue." Id.; see also Gen. Dynamics Land Sys., Inc. v Cline, 540 U.S. 581, 600 (2004). If Congress directly spoke to and addressed the issue, then the agency's

interpretation must give effect to the “unambiguously expressed intent of Congress.” Chevron, 467 U.S. at 843. If, however, the statute is silent or ambiguous, then the court must inquire as to whether “the agency’s answer is based on a permissible construction of the statute.” Id. The court may not substitute its own construction of the statute at issue, nor can it defer to an agency construction of the statute that is “arbitrary, capricious, or manifestly contrary to the statute.” Id. at 843–44; see also Ctr. for Legal Advocacy v. Hammons, 323 F.3d 1262, 1267 (10th Cir. 2003).

The Supreme Court has clarified the scope of deference applicable to an agency’s interpretation of a statute by limiting such deference to formal adjudication and notice-and-comment rulemaking. See Christensen, 529 U.S. at 586. In doing so, the Court explained that “interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law, do not warrant Chevron-style deference.” Christensen, 529 U.S. at 586. The Supreme Court noted, however, that agency interpretations contained in such documents are “entitled to respect” to the extent they have the “power to persuade.” Id. (citing Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

When agencies interpret their own regulations, including relevant procedural rules, the Tenth Circuit Court of Appeals has determined that such interpretations “[are] entitled to great deference” and will be denied only “if it is unreasonable, plainly erroneous, or inconsistent with the regulations’ plain meaning.” Bar MK Ranches, 994 F.2d at 738 (citing City of Gillette, Wyoming v. FERC, 737 F.2d 883, 884–85 (10th Cir. 1984)).

II. PLAINTIFFS LACK APPROPRIATE STANDING TO CHALLENGE THE GRANT OF INSPECTION ISSUED TO RESPONSIBLE TRANSPORTATION

Preliminarily, Plaintiffs have failed to adequately allege that they have standing with regard to their claims regarding Responsible Transportation. Plaintiffs state that they “clearly have standing to bring this action because they will be directly affected by the grant of inspection and residue program and by the USDA’s actions challenged here.” Document No. 170 at 27, n. 14. In support, Plaintiffs cite to several declarations demonstrating their standing; however, Plaintiffs fail to cite to or provide any declaration that could provide support for standing as it pertains to the Responsible Transportation.

Indeed, the only reference in Plaintiffs' Opening Brief or their First Amended Complaint to any plaintiff near or relevant to the Responsible Transportation facility states:

25. HSUS member Barbara Mohror became a member of The HSUS so that it would represent her interests on animal protection issues, including the slaughtering of horses for human consumption. Ms. Mohror has lived in Keota, Iowa for more than eighteen years. Ms. Mohror recreates with her family in the Sigourney area, and will be injured if Responsible Transportation begins horse slaughter operations.

Document. No. 54, at ¶ 25. Presumably, Plaintiff HSUS is pursuing the challenge to Responsible Transportation's grant of inspection by asserting that it maintains the appropriate "organizational" standing.

Under the "organizational" theory of standing, an organization has standing to pursue a claim on behalf of its members when: "(1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose; and (3) neither the claims attested nor the relief requested requires the participation of the individual members in the lawsuit." Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 342 (1997); see also Sierra Club v. Morton, 405 U.S. 727, 739 (1972) (noting

that “a mere ‘interest in a problem’ no matter how longstanding the interests and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization ‘adversely affected’ or ‘aggrieved’ within the meaning of the APA.”).

Here, Plaintiffs have failed to demonstrate that any member, including Ms. Mohrer, would have standing to sue in their own right to challenge Responsible Transportation’s grant of inspection. Defendant-Intervenors can locate no affidavit or declaration demonstrating that Ms. Mohrer meets “the irreducible constitutional minimum of standing.” Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). To maintain standing, a plaintiff must show (1) an “injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) ‘actual or imminent, not ‘conjectual’ or ‘hypothetical’”; (2) “a causal connection between the injury and the conduct complained of—the injury has to be ‘fairly ... trace[able] to the challenged action of the defendant, and not ... th[e] result [of] the independent action of some third party not before the court’”; and (3) “it must be ‘likely,’ as opposed to merely ‘speculative,’ that the injury will be redressed by a favorable decision.” Id. at 560–61 (internal citations omitted).

In order to successfully establish “injury in fact,” the plaintiffs must prove with “the manner and degree of evidence required at the successive stages of the litigation,” *Id.* at 561, that the injury is “actual or imminent.”² In *Lujan*, the Supreme Court held that an “affiants ‘profession of inten[t] to return to the places they have visited before . . . is simply not enough” because “‘some day’ intentions” absent any “description of concrete plans” or “specification of when some day will be” are not sufficient to “support a finding of ‘actual or imminent’ injury that our cases require.” *Id.* at 564.

The same standard is applicable here, where Plaintiffs’ only statement in support of injury in fact is limited to one sentence stating “Ms. Mohror recreates with her family in the Sigourney area.” Absent some measure of proof – i.e. an affidavit or declaration – stating “a description of concrete plans” or even “the specification of when” they plan to recreate near the Responsible Transportation facility, the Plaintiffs’ averment of harm lacks the substance necessary to meet the “irreducible constitutional minimum of standing.” *Id.* at 560.

² The Supreme Court expressed that “[w]hen the plaintiff is not himself the object of government action or inaction he challenges, standing is not precluded, but it is ordinarily ‘substantially more difficult to establish.’” *Lujan*, 504 U.S. at 562 (citing *Allen v. Wright*, 468 U.S. 757, 758 (1984)).

III. PLAINTIFFS' CLAIM THAT THE FEDERAL DEFENDANTS VIOLATED NEPA BY FAILING TO CONDUCT SUFFICIENT ENVIRONMENTAL REVIEW PRIOR TO ISSUING A "NEW DRUG RESIDUE PROGRAM" IS NOT A COGNIZABLE CLAIM UNDER THE APA

A. Federal Defendants' "New Drug Residue Program" is Not a Discrete Agency Action Subject to Review Under the APA

Plaintiffs and Plaintiff-Intervenor assert that the Federal Defendants violated NEPA and the APA by failing to undertake NEPA review concerning the "new drug residue program." The challenge fails because it does not pertain to a "discrete" agency action and, therefore, it is not a cognizable under the APA. In fact, challenges to such broad, generalized, and programmatic actions are the type explicitly prohibited by the Supreme Court's decision in Lujan v. National Wildlife Federation, 497 U.S. 871 (1990).

There, the Supreme Court reversed the lower courts' grant of a blanket injunction suspending the Bureau of Land Management's "land withdrawal review program." Id. at 879–80, 900. The National Wildlife Federation had asserted, among other things, that the BLM's management of the land withdrawal program – the ongoing process of deciding whether public land withdrawals should be

continued or terminated – was flawed by its failure to prepare proper environmental review pursuant to NEPA. Id. at 879.

The Supreme Court first stated that BLM’s “program”:

is not an “agency action” within the meaning of § 702, much less a “final agency action” within the meaning of § 704. The term “land withdrawal review program” * * * does not refer to a single BLM order or regulation, or even to a completed universe of particular BLM orders and regulations. It is simply the name by which [the federal agencies] have occasionally referred to the continuing (and thus constantly changing) operations of the BLM in reviewing withdrawal revocation applications and the classifications of public lands and developing land use plans as required by [law].

Id. at 890. Accordingly, and despite the fact that BLM took specific actions under its program, the Supreme Court held that “it is at least entirely certain that the flaws of the entire ‘program’—consisting principally of the many individual actions referenced in the complaint and presumably actions to be taken—cannot be laid before the courts for wholesale correction under the APA.” Id. at 892–93; See also Found. on Econ. Trends v. Lyng, 943 F.2d 79, 86 (D.C.Cir. 1991) (dismissing plaintiffs’ NEPA and APA claims against the USDA’s germplasm preservation program because the program was no more identifiable than the Land Withdrawal program in Lujan).

These cases are directly on point with the Plaintiffs' current claim before this Court – that FSIS erred by failing to undertake NEPA review for its “New Residue Testing Program.” The “New Drug Residue Testing Program” is not a discrete, identifiable action or decision. Instead, the Plaintiffs' challenge to the “New Residue Testing Program” represents an overly broad, overly generalized attempt to attack FSIS' programmatic effort to implement its statutory mandate to “prevent the use in commerce of meat and meat food products which are adulterated.” FMIA, 21 U.S.C. § 603(a).³ Currently, FSIS utilizes a myriad of directives, guidance and other instructional documents to carry out its statutory mandates, including residue sampling and testing.⁴ Thus, even assuming some

³ This attempt is a small portion of the much larger HSUS blitzkrieg attack directed at the entire animal agriculture industry. HSUS is pursuing its agenda with gladiatorial passion and determination, whether through rulemaking, lobbying, litigation, or propaganda. See, e.g., AR1–1164 (HSUS petition for rulemaking and attached exhibits).

⁴ The relevant directives comprise at least eleven Directives contained in the Administrative Record, and also include many not in the record. See, e.g., FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program, AR635; FSIS Notice 40-11, Instructions for Carcass Selection of the National Residue Scheduled Samples, AR655; CLG-AMG2.06, Screening and Confirmation for Aminoglycosides by LL-MS-MS, AR2040; GLG-CAM1.03, Screening for Cloramphenicol by ELISA, AR2076; CLG-PBZ3.03, Screening for Phenylbutazone by ELISA, AR2156.

alleged flaws with the program, it is “entirely certain that [any alleged] flaws of the entire ‘program’ . . . cannot be laid before the courts for wholesale correction under the APA.” Lujan, 497 U.S. at 892–93.

By failing to direct the challenge to a discrete, identifiable agency action, Plaintiffs fail to demonstrate a cognizable claim under the APA.

B. Federal Defendants’ Directive 6130.1 is Not a Final Agency Action Subject to Review Under the APA

Even assuming that Plaintiffs are directly challenging FSIS Directive 6130.1, Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks (“Directive”), as it *now* appears, then such a challenge still falls short of the standards laid forth by the APA and more fully expounded upon by the courts. Here, Plaintiffs’ cite to no statutory authority which would provide for review of Directive. Thus, the agency’s development of the Directive is only reviewable if it constitutes “final agency action for which there is no other adequate remedy in a court.” 5 U.S.C. § 704. Because Plaintiffs cannot show that the Directive is a “final agency action,” then Plaintiffs again fail to articulate a cognizable claim under the APA.

An agency action is “final” for purposes of review under the APA when two conditions are satisfied. “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, 520 U.S. at 177–78; see also Ctr. for Native Ecosystems v. Cables, 509 F.3d 1310, 1329 (10th Cir. 2007); and Impact Energy Res., LLC v. Salazar, 693 F.3d 1239, 1253–54 (10th Cir. 2012). The failure to meet either condition means there is no final agency action subject to judicial review under the APA. Based on this clear definition, the Directive is not a “final agency action.”

The Tenth Circuit noted that the Supreme Court has “interpreted the ‘finality’ element in a pragmatic way.” Ctr. for Native Ecosystems, 509 F.3d at 1329 (citing FTC v. Standard Oil of Cal., 449 U.S. 232, 239 (1980)). Applying the Bennett conditions pragmatically, we cannot assume that the Directive serves to consummate the agency’s decision making process. The Directive is clearly a statement of the agency’s inspection instructions, but it does not represent the last word on the residue testing program because many of the relevant provisions are addressed in other directives. Further, the Directive’s language acknowledges that

the final statement for equine inspection is not yet available. See, e.g. AR1869 (noting that inspectors seeking guidance may refer to other applicable directives “until such information for equine is provided in a revised or new issuance”).

Accordingly it is difficult to see how the Directive could constitute the last word regarding the residue testing program. See Ore. Natural Desert Ass’n v. U.S. Forest Serv., 465 F.3d 977, 984 (9th Cir. 2006).

Moreover, the Directive does not determine rights or obligations, as is required by the second prong of the Bennett analysis. Neither is the Directive the cause of any legal consequences, as Plaintiffs argue. Pragmatically, the Directive cannot be viewed as anything more than general operating instructions because it very clearly is nothing more than an internal, instructional document for both inspection program personnel and FSIS Public Health Veterinarians. In fact, the “Purpose” section of the Directive plainly states:

[t]his directive provides instructions to inspection program personnel (IPP) on how to perform ante-mortem inspection of equines before slaughter and post mortem inspection of equine carcasses and parts after slaughter. Additionally, this directive instructs Food Safety and Inspection Service (FSIS) Public Health Veterinarians (PHVs) 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 using the Public Health Inspection System for equine when available.

AR1861 (emphasis added).

Thus, the Directive, in individual sections and in whole, serves as a “how to” for FSIS inspectors to carry out their day-to-day activities at the processing facilities. As an instructional document, the Directive is not binding on the agency, not enforceable in court, and certainly does not determine any rights or obligations. See, e.g., Schweiker v. Hansen, 450 U.S. 785, 789–90 (1981) (holding that a federal agency’s instructional manual “is not a regulation[,], has no legal force, and it does not bind the [federal agency]”); W. Radio Servs. 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 independent force and effect of law”).

Despite the pragmatic analysis outlined above, the Plaintiffs attempt to characterize the Directive as a final agency action by claiming that the Directive determines the “right of slaughter facilities to be inspected and commence operations,” that “failure to comply with its standards may result in penalties,” and,

that “the Agency relied on the Directive in both of its CE Memos.” Doc. No. 170, at 29.⁵

In this instance, it is difficult to envision how failure to comply with the Directive – which only informs how inspectors should satisfy their obligations under the FMIA and its implementing regulations – will itself result in penalties for an inspected facility or any relevant individual. The Directive is absent any real substantive enforcement provisions. The only mention of enforcement notes that inspectors, upon receipt of test results from the lab, are to make final disposition on the carcass and parts and take any necessary regulatory enforcement action based on the results,” AR1868 (emphasis added). Thus, regulatory action is based on a sample’s failed test result not an entity’s failure to comply with the Directive.⁶

⁵ In support, Plaintiffs rely almost exclusively on the language from this Court’s TRO Order; however, “the findings of fact and conclusions of law made by a court granting a preliminary injunction are not binding at trial on the merits.” Herrera v. Santa Fe Pub. Sch., 792 F.Supp.2d 1174, 1179 (D.N.M. 2011) (citing Att. Gen. of Okla. v. Tyson Foods, Inc., 565 F.3d 769, 776 (10th Cir. 2009)).

⁶ Notably, other FSIS inspection directives (including those relevant to equine processing) maintain explicit provisions concerning compliance and enforcement against others. See, e.g., FSIS Directive 10,800.1, Procedures for Residue Sampling, Testing, and Other Responsibilities for the National Residue Program (including the right of inspection personnel to “document the noncompliance” and “issue an NR”), AR635; FSIS Directive 5000.1, Verifying an Establishments’

Here, Plaintiffs' citations also prove unpersuasive because they concern actions with direct and binding effect on others. See W. Ill. Home Health Care, Inc. v. Herman, 150 F.3d 659, 663 (7th Cir. 1998) (decision letter characterizing employees, outlining obligations and referencing penalties); Ore. Natural Desert Ass'n, 465 F.3d at 986–87 (annual operating instructions defining scope and restrictions of grazing permittees' right to graze public lands); Ciba-Geigy Corp. v. U.S.E.P.A., 801 F.2d 430, 435–36 (D.C. Cir. 1986) (notice from EPA to registrants directing a change in their pesticide labeling requirements). Here, in contrast, the Directive operates only as an internal document informing the actions of employees. See W. Radio Services Co., Inc., 79 F.3d at 901.

Although FSIS references the Directive in the categorical exclusion memos for Valley Meat, Responsible Transportation, and Rains, each memo is quite clear that the Directive is one of many instructional documents to be relied upon when performing inspections. The categorical exclusion decision memos plainly state:

All FSIS inspectors will perform these duties in accordance with the policies and procedures set forth in several FSIS directives and notices, including but not limited to FSIS Directive 6900.2, Rev.2,

Food Safety System at 75 (outlining HACCP Non-Compliance Determinations), AR1910.

Humane Handling and Slaughter of Livestock; FSIS Directive 6100.1, Ante-Mortem Livestock Inspection; FSIS Directive 6100.2, Post-Mortem Livestock Inspection; and FSIS Directive 6130.1, Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks.

AR2469 (emphasis added); AR3284 (emphasis added); AR4870 (emphasis added). Thus, FSIS will rely on policies and procedures outlined in multiple directives to inform *how* the inspectors will satisfy their statutory and regulatory obligations at equine processing facilities.

Plaintiffs appear to more specifically reference the Decision Memos' explanation that "FSIS has addressed th[e] [residue] risks [raised by HSUS] by implementing a new drug residue testing program that will screen the meat of slaughtered horses for drug residues before the meat is allowed to enter the food supply chain (see FSIS Directive 6130.1, Ante-mortem, Post-mortem Inspection of Equines and Documentation of Inspection Tasks).” AR2471; see also AR3285 and AR4873. However, the memos' reference to the Directive simply provides notice that the Directive is the instructional document, which guides equine facility inspectors through their day-to-day tasks implementing the inspection program.

This observation is clarified further upon an examination of the Directive's language. The Directive's section concerning "Residue Testing of Equine" provides explicit directions, noting which FSIS Directives to follow for specific acts, including: sampling rates, sample collection, and documentation of tasks. AR1866-1867. Nowhere, however, does the Directive provide substantive information concerning what residues are tested or how the samples are tested, as that information is provided in *other* directives.⁷

Ultimately, therefore, FSIS does not rely upon the Directive any more than the panoply of other directives currently followed, utilized and incorporated into the CE Decision Memos. To the extent the Directive is relied upon, it is there to document *how* FSIS inspection personnel intend to implement the inspection services, monitor humane handling, collect samples, document tasks, and comply with the larger residue program.

Finally, Plaintiffs claim that the Directive determines the "right of slaughter facilities to be inspected and commence operations." It is here, that Plaintiffs'

⁷ See generally, United States Dep't of Agric., Food Safety and Inspection Serv., FSIS Constituent Update (June 28, 2013) (explaining that "FSIS has modified several Chemistry Laboratory Guidebook Methods to add equine muscle") AR3038.

argument strays furthest from the law. As discussed above, it is the FMIA and the implementing regulations that determine the right of any particular facility to be inspected. See 21 U.S.C. §§ 603–605 (requiring inspection services); see also 9 C.F.R. §§ 304.1–304.3 (explaining that an application is to be submitted before inspection is granted; denoting what information is to be provided; and, outlining the conditions for receiving inspection). The Directive is not among the conditions necessary for FSIS to grant inspection, and the statutes and regulations provide no discretion to agency personnel to refuse or deny a grant of inspection based on the presence or sufficiency of the Directive. In fact, there are a limited number of reasons providing for refusal of inspection. See 9 C.F.R. §§ 304.3(b) and 500.7(a)(1)–(5).

The Directive does serve a necessary and important purpose, but it is merely a “judgment” regarding what processes are necessary to determine “whether carcasses of [equines] are not adulterated, can be passed for human consumption, and are eligible to bear the mark of inspection.” AR1861 (citing 21 U.S.C. § 604). There is no dispute that the agency’s exercise of judgment “does not grant [the agency] the discretion to add another entirely separate prerequisite” to its list. See Nat’l Ass’n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 672 (2007).

Thus, it is altogether evident that the any discretion awarded to FSIS to provide or deny a grant of inspection does not include or rely on the presence of Directive 6130.3. Furthermore, it is equally evident that the Directive is nothing more than an internal “judgment” ensuring that the FMIA is fulfilled and informing FSIS inspectors on how to fulfill it.

C. Even if Plaintiffs’ Challenge to Directive 6130.1 Represents a Cognizable Claim under the APA, the Requirements of NEPA Remain Inapplicable to the Directive

Even if Plaintiffs’ challenge to the “new drug residue program” or the Directive represented a cognizable claim under the APA, issuance of the Directive is not an action that would trigger any obligation under NEPA. The Directive is simply not the “legally relevant cause” of any effect on the environment, as is it must be in order to trigger review under NEPA. See Dep’t. of Transp., 541 U.S. at 770.

Plaintiffs argue that the USDA’s reliance on and incorporation of the Directive in the grant of inspection renders the Directive binding and, therefore, a legally relevant cause. The Plaintiffs’ correlation is misguided. The Directive is binding only on FSIS inspectors insomuch as it informs them how to perform their job. However, it is not binding on others. W. Radio Services Co., Inc., 79 F.3d at

901. More importantly, the Directive is not binding on those FSIS decisionmakers reviewing the grant of inspection to ensure that it meets the necessary requirements. See 9 C.F.R. §§ 304.2-304.3 and 500.7.

The Directive also does not practically pertain to the issuance of any grant of inspection. Rather, it serves only as the operating manual, providing practical instruction to FSIS inspectors so that they may satisfy their ministerial obligations under the FMIA and its implementing regulations after the grant is already issued. The Plaintiffs' and Plaintiff-Intervenor's claim that the USDA can utilize it to "countermand" the alleged harm by "testing for all substances regularly administered to horses" or adopting the system requested in Plaintiffs' Petition for Rulemaking, quite plainly misrepresents the purpose of Directive. Document No. 170 at 29. The Directive does not outline what substances are tested or how they are tested. But see, infra n. 4 and n. 7 (referencing the documents that actually outline the substances tested for and their testing methods).

Finally, as discussed above, the Directive is not and cannot be a legal prerequisite to the grant of inspection. Pursuant to the FMIA and applicable regulatory regime, the grant of inspection is a procedural process whereby inspection must be granted unless one of a limited number of enumerated

conditions is not met. See 21 U.S.C. §§ 603–605 and 671; see also 9 C.F.R. §§ 304.2(b) and 500.7. The limited authority to deny a grant of inspection is not altered by the agency’s judgment that the Directive will help inform how inspectors satisfy their obligation to ensure meat produced at *any* equine processing facility is “wholesome, not adulterated, and entitled to bear the legend ‘inspected and passed.’” See 64 Fed. Reg. 66541, 66542.

In this instance, FSIS’s decisions to issue the grants of inspection were based solely on its evaluation and determination that the Valley Meat and Responsible Transportation applications complied with all statutory and regulatory requirements. See AR3283-3284; AR2469; see also AR4870 (the Rains categorical exclusion decision memo explaining FSIS ministerial function and discretion). Even assuming the Directive was considered when the agency reviewed the applications for a grant of inspection, that consideration “does not confer discretion to ignore the required procedures of decisionmaking.” Bennett, 520 U.S. at 172.

It is therefore apparent that the Directive is not the type of document or decision requiring NEPA evaluation and review. Practically speaking it is nothing more than an internal instruction document. Legally, the Directive cannot be added to the limited conditions considered by FSIS when evaluating a grant of

inspection, see Nat'l Ass'n. of Homebuilders, 551 U.S. at 672, and, therefore, the Directive cannot serve as the legal prerequisite.

IV. FEDERAL DEFENDANTS' ISSUANCE OF GRANTS OF INSPECTION WERE MANDATORY ACTIONS, NOT SUBJECT TO NEPA ANALYSIS

Plaintiffs insist that FSIS violated NEPA by failing to engage in the analysis for and preparation of an environmental assessment ("EA") or environmental impact statement ("EIS"). However, FSIS' issuance of grants of inspection to Valley Meat and to Responsible Transportation (and the likely issuance to Rains) were not discretionary actions which were subject to the procedural requirements of NEPA.

The analysis of alternatives "is characterized as 'the heart' of" the NEPA process. Wyoming v. U.S. Dept. of Agric., 661 F.3d 1209, 1243 (10th Cir. 2011). In an EIS, the agency must "rigorously explore and objectively evaluate all reasonable alternatives" in response to a "specified . . . purpose and need." Id., citing 40 C.F.R. §§ 1502.13, 1502.14(a); see also New Mexico ex rel. Richardson, 565 F.3d at 703 (stating that "an EIS must 'rigorously explore and objectively evaluate' all reasonable alternatives to a proposed action, in order to compare the environmental impacts of all available courses of action."). As discussed above,

the FSIS grant of inspection is a non-discretionary action. This is in keeping with congressional intent -- that any facility, whether slaughtering, packing, meat-canning, rendering, or similar, that processes meat shall have inspectors. The Secretary “shall cause to be made by inspectors appointed for that purpose . . . an examination and inspection.” Id. §§ 603(a) and 604 (emphasis added). The statutory language leaves little room for FSIS to deny, withhold or withdraw such inspections.

FSIS was clear that, though it engaged in analysis to apply the categorical exclusion to its decision to issue grants of inspection to Valley Meat, Responsible Transportation, and Rains, it did not believe that NEPA was applicable to those decisions. See AR 2469-2470; see also AR 3283-3284 and AR4869-4872. For example, in the Decision Memo for the application of the categorical exclusion to Valley Meat’s grant of inspection, FSIS stated:

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 major federal action that triggers NEPA requirements. A grant of federal meat 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 a major federal action that is subject to NEPA requirements.

AR 2469. Therefore, if FSIS has no discretion to deny the grant of inspection, or to choose among other alternative actions, the application of NEPA – where “the heart of” its procedures, the discussion of alternatives, cannot take place – would be meaningless.

Plaintiffs and Plaintiff-Intervenor argue that the issuance of grants of inspection are major Federal actions subject to NEPA review, because they allege that the grant is “the approval of [a] specific project.” See Document No. 170, at 33; Document No. 172, at 16. However, the Plaintiffs fail to grasp the distinction between a discretionary grant of a permit versus the non-discretionary grant of inspection that is present in this litigation. The cases cited by the Plaintiffs in support of their argument indicate that there is a fundamental disconnect between the projects that are discussed in the cited cases and the grants of inspection at issue here: each and every case cited by the Plaintiffs was reviewing a discretionary agency action, where the agency at issue had the ability to choose between several alternatives. See Ramsey v. Kantor, 96 F.3d 434, 444 (9th Cir. 1996) (discussing whether issuance of incidental take statements allowing harvest

of salmon were subject to NEPA); see also Robertson v. Methow Valley Citizens Council, 490 U.S. 332, 336 (1989) (discussing whether issuance of special use permit was a major federal action subject to NEPA); Friends of the Earth, Inc. v. U.S. Army Corps of Eng'rs, 109 F. Supp. 2d 30, 40 (D.D.C. 2000) (discussing whether issuance of casino river barge permits was a major federal action subject to NEPA); Macht v. Skinner, 916 F.2d 13 (D.C. Cir. 1990) (discussing whether federal involvement in state light rail project made the project a major federal action subject to NEPA); Davis v. Morton, 469 F.2d 593, 596-97 (10th Cir. 1972) (whether grant of long-term lease on tribal lands constituted major federal action subject to NEPA). Not a single case cited by the Plaintiffs involves a non-discretionary action, where the analysis of alternatives would be fruitless.

The application of NEPA to the decisions to issue grants of inspection is markedly different than the decision which was considered in Humane Society v. Johanns, a case repeatedly relied upon by the Plaintiffs. See Humane Society v. Johanns 520 F. Supp. 2d 8 (D.D.C. 2007). In Johanns, the United States District Court for the District of Columbia considered whether a fee-for-service program established by FSIS through an interim final rule pursuant to the Agricultural Marketing Act (“AMA”) was subject to NEPA. See id. at 12-13. Ultimately, the

court in Johanns determined that the fee-for-service program *was* subject to NEPA analysis because the rule was the “legally relevant cause” of the environmental effects of the horse slaughter facilities. See id. at 27. The court noted that, following the 2006 Appropriations Amendment which prohibited funding for inspections under the FMIA, no further inspections could take place under the FMIA. Therefore, FSIS promulgated the interim final fee-for-service rule pursuant to the AMA in an attempt to allow inspections to continue. See id. The court held that there was no requirement that, although inspections pursuant to FMIA were mandatory, see id. at 26, FSIS had discretion in choosing to implement the interim final fee-for-service rule – a rule which was not required by (and was, in fact, contrary to) FMIA. See id. at 27.

Plaintiffs entirely misrepresent the Johanns holding, arguing that “USDA is the ‘legally relevant cause’ of the environmental impacts of the slaughter facilities.” See Document 170, at 34. First, “USDA” cannot be a “legally relevant cause.” USDA is an agency performing a multitude of functions and agency actions – Plaintiffs cannot challenge the entire agency as the “legally relevant cause.” Second, the decision under appeal in this case is wholly different than that challenged in Johanns, a fact which the Johanns court recognized and used to

distinguish the rule at issue in that case. See Johanns, 520 F. Supp. 2d at 26. The Johanns court noted that FMIA contains a non-discretionary command to FSIS to provide inspectors to examine and inspect all amenable species, and for the United States to pay for those inspections. See id. at 27. It then contrasted the fee-for-service program as being non-discretionary, contrary to FMIA, and the sole legal basis for which inspections would occur.

FSIS has properly determined that it lacks discretion over whether to issue grants of inspection if the applicant has met all of the necessary requirements, and if none of the factors enumerated in the exhaustive list of substantive determinations that may provide grounds to deny a grant of inspection are present. See 9 C.F.R. §§ 304.2 and 500.7. This determination is entitled to judicial deference, as it is a federal agency interpreting its own statutory authorities. See Chevron U.S.A., 467 U.S. at 843-44 (holding that judicial review of an administrative agency's construction of the statutes that it administers is limited and deferential).

In issuing grants of inspection to Valley Meat and Responsible Transportation, FSIS determined that none of these factors were present, that the facilities had met all of the requirements for the grants of inspection, and that

therefore, it was required to issue grants of inspection. Due to the agency's lack of discretion, NEPA is inapplicable to the grants of inspection.

V. EVEN IF FEDERAL DEFENDANTS' GRANT OF INSPECTION WAS SUBJECT TO NEPA ANALYSIS, CATEGORICAL EXCLUSION WAS PROPERLY APPLIED

Although FSIS did not concede that *any* analysis pursuant to NEPA was required in order to issue a grant of inspection to the Valley Meat, Responsible Transportation, or Rains facilities, the agency went through the process of evaluating whether – if NEPA were applicable – the grant of inspection would fall within the categorical exclusion for the agencies' activities. This analysis was far from a rubber-stamp on the process. Rather, the agency engaged in careful consideration of the potential effects of its action, and determined that a categorical exclusion was warranted.

“Categorical Exclusion” is defined by CEQ regulations as:

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 in procedures adopted by a Federal agency in implementation of these regulations (§ 1507.3) and for which, therefore, neither an environmental assessment nor an environmental impact statement is required. . . . Any procedures under this section shall provide for extraordinary circumstances in which a normally excluded action may have a significant environmental affect.

40 C.F.R. § 1508.4.

The USDA's implementing regulations for NEPA list FSIS as an agency that conducts programs and activities that have been found to have no individual or cumulative effect on the human environment. See 7 C.F.R. § 1b.4(b)(6).

Therefore, FSIS is categorically excluded from the requirements of preparing procedures to implement NEPA, and its actions are categorically excluded from the preparation of an Environmental Assessment ("EA") or Environmental Impact Statement ("EIS") unless the FSIS Administrator determines that an action may have a significant environmental effect. See id.; see also 7 C.F.R. § 1b.3(c). In accordance with these regulations, FSIS issued Decision Memos discussing its application of the categorical exclusion to the Valley Meat, Responsible Transportation, and Rains facilities. See AR 2466-2553 (Decision Memo on Categorical Exclusion for Valley Meat); see also AR 3281-3320 (Decision Memo on Categorical Exclusion for Responsible Transportation) and AR 4868-4878 (Decision Memo on Categorical Exclusion for Rains).

In reviewing the FSIS decision to utilize a categorical exclusion for its grants of inspection, the question is not whether the FSIS should have used an EIS or an EA instead of a categorical exclusion. See *Wildearth Guardians v. U.S.*

Forest Serv., 668 F. Supp.2d 1314, 1333 (D.N.M. 2009), citing Casias v. Sec's of Health and Human Servs., 933 F.2d 799, 800 (10th Cir. 1991) (“In evaluating the appeal, we neither reweigh the evidence nor substitute our judgment for that of the agency.”). Rather, the question before the Court is whether the categorical exclusions were supported by reasonable facts and conclusions. See id. Further, “an agency’s interpretation of the scope of one of its own CE’s is ‘given controlling weight unless plainly erroneous or inconsistent with the terms used in the regulation.’” Back Country Horsemen of Am. v. Johanns, 424 F. Supp.2d 89, 99 (D.D.C. 2006) (quoting Alaska Ctr. for Env’t v. U.S. Forest Serv., 189 F.3d 851, 857 (9th Cir. 1999)).

The FSIS analysis for and preparation of a categorical exclusion are yet two additional distinctions between the case at bar and the Humane Society v. Johanns case upon which Plaintiffs’ repeatedly rely throughout their opening brief. One of the major discussions in which the United States District Court for the District of Columbia engaged in that opinion was a discussion related to the fact that FSIS *had not* gone through any analysis or consideration as to whether the Interim Final Rule at issue in that case invoked “extraordinary circumstances” such that it “may have a significant environmental effect,” and that it therefore violated 7 C.F.R. §

1b.4 and NEPA's implementing regulations. 520 F. Supp. 2d at 33-34. Further, in Johanns, the administrative record revealed that the FSIS had not actively invoked the categorical exclusion at any point prior to the litigation, much less engaged in the active preparation of Decision Memos which exist in the present case. See id. The administrative record in the present case clearly demonstrates that the FSIS appropriately considered the scientific data available to it, applied that data to the relevant factors, and made a reasoned, written explanation for each categorical exclusion.

A. No Extraordinary Circumstances precluding use of the categorical exclusion were present.

One significant limitation is placed on the use of categorical exclusion: a proposed action is precluded from categorical exclusion if “extraordinary circumstances” exist such that “a normally excluded action may have a significant environmental effect.” See 40 C.F.R. § 1508.4 (emphasis added); see also Utah Env'tl. Cong. v. Bosworth, 443 F.3d at 736. An extraordinary circumstance exists only where a proposed action “may have a significant environmental effect.” See 40 C.F.R. § 1508.4 (defining categorical exclusion as a category of actions that do not “individually or cumulatively have a significant effect on the human environment.”) (emphasis added). This language plainly requires that an action

first produce a significant effect before a federal agency engages in further analysis. See Utah Env'tl. Cong. v. Bosworth, 443 F.3d at 742.

In Utah Environmental Congress v. Bosworth, the Tenth Circuit demanded more than a *de minimis* impact on resource conditions before an extraordinary circumstance warranted further analysis and documentation in an environmental assessment; in fact, the Tenth Circuit required “a potential for a significant effect” on a resource condition. See 443 F.3d at 742-43 (internal citations omitted); see also Alaska Ctr. for the Env't v. U.S. Forest Serv., 189 F.3d 851, 858 (9th Cir. 1999) (extraordinary circumstances are those circumstances in which a normally excluded action may have significant environmental effect). Further, the Tenth Circuit noted that, “in general, environmental regulations do not place a heavy burden on federal agencies to detail actions which will have only insignificant effects on the health of the environment. For example, ‘a detailed statement by the responsible official on the environmental impact of [a] proposed action’ is required only for ‘Federal actions *significantly affecting* the quality of the human environment....’ 42 U.S.C. § 4332(C).” Utah Env'tl. Cong. v. Bosworth, 443 F.3d at 742 (emphasis in original). This analysis is consistent with the purpose for a categorical exclusion: to promote efficiency in its NEPA review process by

avoiding unnecessary analysis for those agency actions where experience has demonstrated the *insignificance* of effects. See id.

In determining whether an action will “significantly” effect the environment, the CEQ regulations provide certain factors that should be considered. Id. The factors include, among others, (1) the degree to which the proposed action affects public health or safety, (2) the degree to which the effects will be highly controversial, (3) whether the action establishes a precedent for further action with significant effects, and (4) whether the action threatens a violation of Federal, state or local law or requirements imposed for the protection of the environment. 40 C.F.R. § 1508.27(b); see also Alaska Ctr. for Env't, 189 F.3d at 859. Once the agency “considers the proper factors and makes a factual determination on whether the impacts are significant or not, that decision implicates substantial agency expertise and is entitled to deference.” Alaska Ctr. for Env't, 189 F.3d at 857.

Plaintiffs and Plaintiff-Intervenors cite an unpublished United States District of New Mexico case for the proposition that the implication of CEQ significance factors triggers an EIS, or at least a detailed EA. See Document No. 170, at 36; Document 172, at 19, citing Amigos Bravos v. U.S. Bureau of Land Mgmt., 6:09-CV-00037-RB-LFG, 2011 WL 7701433 (D.N.M. Aug. 3, 2011). In fact, the

Amigos Bravos case was one of several cited by the Plaintiffs in which the courts were analyzing whether or not the EA prepared by the specific agency was sufficient, or whether the agency should have gone on to prepare a more fully-developed EIS. See Document 170, at 37, citing Fund for Animals v. Norton, 281 F. Supp.2d 209, 235 (D.D.C. 2003) and Town of Superior v. U.S. Fish & Wildlife Serv., 913 F. Supp.2d 1087, 1120 (D. Colo. 2012). The analysis of whether an agency has successfully completed its NEPA requirements through an EA, versus whether an agency can appropriately avoid the NEPA process by relying on a categorical exclusion, is not analogous. In order for a categorical exclusion to be inappropriate for a given agency activity, the agency must find that there is an *extraordinary circumstance* which might result in a *significant* effect on the environment.

In Amigos Bravos, the Court noted that CEQ regulations “provide agencies with some guidance on what constitutes a ‘significant impact’ by establishing factors to determine the intensity of an impact.” See id. at *20. Further, the Court noted that, in addition to the “intensity” factors included in 40 C.F.R. § 1508.27(b), subsection (a) of the same regulation instructs the Court to look at the “context” of the proposed action. Far from requiring an EIS or a “detailed EA” upon the

existence of any significance factors, this Court recognized that, even if those factors were present, the agency could apply them in terms of “intensity” and “context.” Therefore, even if any of the CEQ significance factors are implicated, it is within the agency’s expertise to determine whether the implicated factor rises to the level of an extraordinary circumstance, or said another way, whether the issue might cause a significant impact on the environment.

Although FSIS contemplated the effects of issuing grants of inspection to Valley Meat, Responsible Transportation, and Rains, the agency did not find that issuing these grants would produce any significant effects, and certainly none that rose to the level of being an extraordinary circumstance. See AR 2476 (“FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant federal meat inspection services to Valley Meat that would cause this action to have a significant environmental effect.”); see also AR 3289 (“FSIS finds no unique or extraordinary circumstances of the proposed action to grant federal meat inspection services to Responsible Transportation that would cause this action to have a significant environmental effect.”) see also AR 4879 (“FSIS finds no unique conditions or extraordinary circumstances of the proposed action to grant

federal meat inspection services to Rains Natural Meats that would cause this action to have a significant environmental effect.”).

Plaintiffs allege that several “significance factors” were implicated by the decision to grant inspection to Valley Meat and to Responsible Transportation (and the likely decision to grant inspection to Rains), and that FSIS improperly determined that these implicated factors were not cause for NEPA analysis. However, FSIS properly came to the conclusion that, even if some of these factors were implicated to a degree, none of those issues rose to the level of an extraordinary circumstance which would make the categorical exclusion inapplicable.

The first factor that the Plaintiffs point to as mandating a NEPA analysis is the degree to which the FSIS decision to grant an inspection will affect public health and safety. See Document No. 170, at 36, citing 40 C.F.R. § 1508.27(b)(2), (5); see also Document No. 172, at 19. This factor was analyzed in depth by FSIS in its Categorical Exclusion Decision Memos. See AR 2471; see also AR 3285-3286 and AR 4872-4874. FSIS stated that federal inspection pursuant to the FMIA is “intended solely to protect public health and safety by ensuring that meat and meat food products intended for use as human food are not adulterated or

misbranded.” See AR 2471, 3285, and 4872 . It noted that it had procedures in place which would render any horse meat that tested positive for any drug residue to be marked “U.S. condemned,” and would not be allowed to enter into the stream of commerce. See AR 2471, 3286, and 4873. Further, FSIS noted that an overlapping scheme of federal, state and local environmental laws and ordinances would further ensure that waste products generated by the processing facilities would be properly disposed of and that it would not enter into the human food supply chain or the local environment. See id.; see e.g. AR 2570 (FSIS letter to Valley Meat requesting certification that will not discharge into navigable waters in violation of Clean Water Act); AR 2467 (Valley Meat response certifying under penalty of law that it will not discharge into any navigable waters); AR 2608-2613 (EPA certification of no exposure); AR 2740-2742 and AR 2736-2738 (emails between FSIS and State of New Mexico Environment Department ensuring that composting activities were within legal limits). FSIS noted that “a decision to grant federal inspection to Valley Meat will safeguard public health and safety by ensuring 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.” See AR 2471; see also AR 3286 (same re: Responsible Transportation) and AR 4874 (same re: Rains).

This significance factor was one which the Court in Amigos Bravos specifically addressed. There, the Court noted that 40 C.F.R. § 1508.27(b)(2) instructs the Court to look at the “degree” to which the action will affect human health. See Amigos Bravos v. U.S. Bureau of Land Mgmt., 6:09-CV-00037-RB-LFG, 2011 WL 7701433, at *20. In the Categorical Exclusion Decision Memos, FSIS properly considered the “degree” to which its decision would affect public health, and determined that between the drug residue testing program implemented by the facilities themselves (which had to go through an approval process by FSIS), see AR 3206-3210, 3186-3191, 2663-2716, 2659, 2660-2662, 4575-4576, 4678, 4670, 4724-4725 (emails related to facility drug residue testing program), procedures that FSIS had in place, and the additional oversight by other federal, state, and local agencies, there was no potential for its decision to have a significant environmental effect.

Plaintiffs next point to the significance factor from 40 C.F.R. § 1508.27(b)(4): the degree to which the effects on the quality of the human environment are likely to be highly controversial. A proposed action is “highly

controversial” if there is a “substantial dispute [about] the size, nature, or effect of the major Federal action;” mere “opposition to a use” is not sufficient. Town of Superior v. U.S. Fish & Wildlife Serv., 913 F. Supp. 2d 1087, 1120 (D. Colo. 2012), citing Native Ecosystems Council v. U.S. Forest Serv., 428 F.3d 1233, 1240 (9th Cir.2005) and Blue Mountains Biodiversity Project v. Blackwood, 161 F.3d 1208, 1212 (9th Cir.1998). Specifically, Plaintiffs allege that FSIS “recognized and summarily dismissed the potential health risks [as well as] the controversy over whether ‘blood produced by commercial horse slaughter will overwhelm any waste water disposal system.’” See Document No. 170, at 38.⁸ As discussed above, FSIS carefully considered whether the grants of inspection had the potential to create significant effects on public health and safety.

Further, FSIS acknowledged and considered the issue of whether the waste water disposal systems in place would be sufficient to dispose of any blood

⁸ In this section of their arguments, as well as in other portions of their briefs, Plaintiffs and Plaintiff-Intervenor rely heavily on citation and reference to extra-record evidence. The Supreme Court has long held that a court’s review of a federal agency administrative decision is limited to the agency administrative record at the time that the agency decision was made. See Fla. Power & Light v. Lorior, 460 U.S. 729, 743-44 (1985); see also 5 U.S.C. § 706. On September 18, 2013, Defendant-Intervenors filed a motion requesting that this Court strike the extra-record citations, as well as the propositions for which they were cited in support.

produced through equine processing. See e.g. AR 2475-2476. There, after noting that Valley Meat used a septic tank and lagoons to dispose of its wastewater and effluent, FSIS stated:

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

AR 2476, n. 6. This thorough analysis of the issue, with a conclusion that "there was no reason to believe" that there would be a problem, is far from "a substantial dispute about the size, nature, or effect of the major Federal action." Rather, this is a clearly reasoned conclusion based on information provided by agency experts.

Third, the Plaintiffs allege that the factor outlined in 40 C.F.R. § 1508.27(b)(6) prohibits the utilization of a categorical exclusion in these particular instances, because “similar or related projects are being contemplated.” The factor outlined in the CEQ regulations makes no such mandate, and in fact, doing so would eviscerate the very purpose behind categorical exclusions. The relevant factor states “the degree to which the action may establish a precedent for future actions *with significant effects* or represents a decision in principle about a future consideration.” 40 C.F.R. § 1508.27(b)(6) (emphasis added). It is clear that the decision to apply a categorical exclusion to one facility does not necessarily mean that FSIS will choose to make the same decision at a later date, with a different facility: FSIS has engaged in separate analyses for the three facilities involved in this litigation. Further, it is important that this factor specifically states that it applies to actions which will create precedent for future actions that *will have significant effects*. FSIS has stated that the issuance of the grants of inspection before this Court will not have the potential for significant effects; however, due to the requirement to evaluate these factors each and every time it invokes the categorical exclusion, it may or may not come to the same conclusion in the future.

Yet again, Plaintiffs rely on inapplicable case law for support of their argument on this point. See Document No. 170, at 39-40, citing Presidio Golf Club v. Nat'l Park Serv., 155 F.3d 1153, 1163 (9th Cir. 1998). In Presidio Golf Club, the Ninth Circuit was analyzing whether an EIS was required prior to building a public clubhouse for a golf course, or whether the existing EA was sufficient. There, the Ninth Circuit determined that the project at bar was a unique, independent project, and did not serve to establish any precedent. See id. The in-depth analysis performed by the Ninth Circuit tells us exactly why this is inapplicable to the case at bar: here, FSIS determined that a categorical exclusion was appropriate, and therefore, the “substantial analytical and evidentiary burdens triggered when a project is ineligible for categorical exclusion” were not triggered in its analysis. See Utah Env'tl. Cong. v. Bosworth, 443 F.3d 732, 742 (10th Cir. 2006). FSIS reviewed the applicable factors in its Decision Memos; however, they were reviewing them to determine whether any of them had the possibility of producing a significant effect that rose to the level of an extraordinary circumstance which would make the categorical exclusion inapplicable. A comparison of the two distinctly different analyses and their requirements is inapposite.

Plaintiffs next allege that a fourth significance factor is implicated: whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment. See Document No. 170, at 40, citing 40 C.F.R. § 1508.27(10); see also Document No. 172, at 24. In the categorical exclusion Decision Memos for Valley Meat, Responsible Transportation, and Rains, FSIS specifically analyzed many Federal, State and local requirements, and determined that the likelihood that the issuance of a grant of inspection would not result in an implication of those laws. See AR 2472-2476 (analysis for Valley Meat); see also AR 3287-3289 (analysis for Responsible Transportation) and AR 4874-4878 (analysis for Rains). Plaintiff points to only one document within the administrative record in support of its argument, and review of this document quickly belies the veracity of that argument. See AR 2570-2571. The document, a letter from FSIS veterinarian Jennifer Beasley-McKean requests that Valley Meat attest that operations at the facility will not result in a discharge into any navigable waters, or to contact the appropriate State agency for a section 401 certification. See id. There is no allegation contained in the letter that Valley Meat has “operated in violation of the Clean Water Act . . . for years” as Plaintiffs imply that the document demonstrates. See Document No.

170, at 40-41; see also Document No. 172, at 25. In fact, as the responding letter from Valley Meat demonstrates, “there has never been nor is there a potential for discharge in to navigable waters of the United States” from the Valley Meat facility. See AR 2567. Therefore, the Plaintiffs allegations with regard to this significance factor are without merit.

Plaintiff-Intervenors raise an additional significance factor not raised by the Plaintiffs: the degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical habitat under the Endangered Species Act of 1973 (“ESA”). See Document 172, at 21, citing 40 C.F.R. § 1508.27(b)(9). FSIS engaged in a significant discussion regarding any possible effects on endangered and threatened species in its categorical exclusion Decision Memos. See AR 2473; see also AR 3281, 3287 (noting that because there was “no effect on endangered species and/or their critical habitats” from the grant of inspection to Responsible Transportation, a separate decision memo for the ESA was not needed) and AR 4876. Regarding Responsible Transportation, FSIS noted that there was no suitable habitat for any species protected by the ESA near the facility, and no species would be adversely affected by the facility. See AR 3287. The categorical exclusion Decision Memos

for Valley Meat and Rains made similar findings, stating that commercial horse slaughter activities at the facilities “will have not have any impact, either directly or indirectly” on any federally or state-protected species. See AR 2473; see also AR4876.⁹ This finding was documented by the United States Fish and Wildlife Service (“USFWS”) in its Decision Memo - Section 7 Consultation on June 27, 2013. See AR 2542-2553. In that document, the USFWS concluded that “issuing a grant of federal inspection services to Valley Meat Company, LLC, will not affect any species listed under the [ESA] or any critical habitat.” See AR 2542.¹⁰

⁹ The Valley Meat Decision Memo also noted that “commercial slaughter for other amenable species [has] occurred more or less continuously at Valley Meat’s facility for more than 20 years with no discernible effects on listed endangered species or their designated critical habitat” and that because the methods for proposed horse slaughter at the facility would not differ significantly than those previously used, “there is no reason to believe that the conversion [of the facility] . . . will have any more impact on endangered species and their critical habitat than did the [previous use of the facility].” See AR 2473.

¹⁰ In its decision document, the USFWS noted that “a decision to grant federal meat inspection services to a commercial horse slaughter plant is not an agency action that triggers a Section 7 consultation under the ESA. If a commercial horse slaughter plan meets all of the statutory and regulatory requirements for receiving a grant of federal inspection services, FSIS must issue the grant, and it does not have discretion to refuse the grant on other grounds.” See AR 2544. However, the USFWS noted that, “given the fact that opponents of commercial horse slaughter have indicated their intention to challenge any grant of federal inspection for commercial horse slaughter at Valley Meat on ESA grounds, FSIS has engaged in informal consultation with [USFWS] concerning the potential effects of commercial horse slaughter on endangered or threatened species and their critical

FSIS – and the USFWS – carefully considered any potential impacts on endangered and threatened species and/or their critical habitat, and determined in their expert opinions that there would not be any impacts.

FSIS carefully considered whether categorical exclusions for its decisions to issue grants of inspection were soundly reasoned, and carefully considered all relevant factors. FSIS, in an application of agency expertise, determined that there were no extraordinary circumstances which would prevent the application of the categorical exclusion to these actions. Therefore, the agency’s determination that it was not required to engage in the preparation of an EA or EIS should be upheld by this Court.

VI. PLAINTIFFS HAVE NOT DEMONSTRATED THAT FSIS IMPROPERLY RELIED UPON POLITICAL CONSIDERATIONS

Plaintiffs’ final argument is that FSIS improperly relied upon political considerations when it made the decisions to apply categorical exclusions to its decisions to issue grants of inspection to Valley Meat and Responsible Transportation. However, Plaintiffs’ attempts to make this argument are misleading at best, and disingenuous at worst.

habitat.” See AR 2545-2546.

In arguing that FSIS relied on political considerations for its decisions, HSUS points to a “Decision Memo” in which FSIS briefly discusses how its actions might be perceived in light of current congressional circumstances. See AR 1829. However, what Plaintiffs fail to mention is that the decision that FSIS was making was how to respond to HSUS’ petition for rulemaking, as well as how the response to that petition would affect what type of inspection system FSIS would implement and when, not its decision to issue grants of inspection. See AR 1823-1829. This was an internal memorandum, considering how to respond to the HSUS petition, and did not discuss – and appears to have had no bearing upon – the decision to utilize the categorical exclusion for the issuance of the grants of inspection.

Moreover, the language which Plaintiffs cite from this internal memorandum is pulled from an option for a course of action *which FSIS did not implement*. See AR 1829. The “cons” discussed in Plaintiffs’ opening brief all fall under a section which discussed the option of postponing ruling on the merits of the HSUS petition (Option 3). See id. However, the administrative record makes it clear that the HSUS petition was denied, and that the agency selected Option 2. See AR 1853-1858.

Therefore, Plaintiffs' allegation that FSIS' decisions related to its issuance of grants of inspection to Valley Meat and Responsible Transportation were improperly based on political consideration is without basis in the administrative record.

CONCLUSION

Based on the foregoing, the Defendant-Intervenors respectfully request that the Plaintiffs' Complaint requesting review of agency action be denied in its entirety, and that the Federal Defendants be deemed to have complied with the National Environmental Policy Act in issuing grants of inspection to Valley Meat Company, LLC and Responsible Transportation, LLC. Further Defendant-Intervenors respectfully request that the agency's decisions to issue grants of inspection be affirmed and upheld in their entireties.

//

//

//

//

//

//

RESPECTFULLY SUBMITTED this 27th day of September, 2013.

/s/Kathryn Brack Morrow

Karen Budd-Falen
Kathryn Brack Morrow
BUDD-FALEN LAW OFFICES, LLC
300 East 18th Street
Post Office Box 346
Cheyenne, WY 82003-0346
(307) 632-5105 Telephone
(307) 637-3891 Telefax
karen@buddfalen.com
kathryn@buddfalen.com
*Attorneys for Defendant-Intervenor
International Equine Business Assn., et al.*

/s/ John W. Boyd

John W. Boyd
Freedman Boyd Hollander
Goldberg Urias & Ward, P.A.
20 First Plaza, Suite 700
Albuquerque, NM 87102
505/842-9960 Telephone
505/842-0761 Telefax
jwb@fbdlaw.com
*Attorney for Defendant-Intervenor
Confederated Tribes and Bands of
the Yakima Nation*

/s/Gary H. Baise

Gary H. Baise
Olsson Frank Weeda Terman Matz PC
600 New Hampshire Ave., NW, Ste 500
Washington, DC 20037
202/789-1212 Telephone
202/234-3550 Telefax
gbaise@ofwlaw.com
*Attorney for Defendant-Intervenor
Confederated Tribes and Bands of
the Yakima Nation*

/s/A. Blair Dunn

A. Blair Dunn
6605 Uptown Blvd. NE
Suite 280
Albuquerque, NM 87710
505/881-5155 Telephone
505/881-5356 Telefax
abdunn@ablairdunn-esq.com
*Attorney for Defendant-Intervenors
Rains Natural Meats,
Chevaline, LLC, Valley Meat
Company, LLC, et al.*

/s/ Patrick J. Rogers

Patrick J. Rogers
20 First Plaza Center #725
Albuquerque, NM 87102
505/938-3335 Telephone
patrogers@patrogerslaw.com
Attorney for Responsible Transportation, LLC

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed.R.App.P. 32(a)(7)(B), because this brief contains 14,411 words, excluding the parts of the brief exempted by Fed.R.App.P. 32(a)(7)(B)(iii).
2. This brief complies with the typeface requirements of Fed.R.App.P. 32(a)(5) and the type style requirements of Fed.R.App.P. 32(a)(6), because this brief has been prepared in a proportionally spaced typeface using Corel WordPerfect X3, Times New Roman type style and size fourteen font.
3. I certify that the information on this form is true and correct to the best of my knowledge and belief formed after a reasonable inquiry.

/s/Kathryn Brack Morrow
Kathryn Brack Morrow
BUDD-FALEN LAW OFFICES, LLC

CERTIFICATE OF DIGITAL SUBMISSIONS

I hereby certify that:

(1) all required privacy redactions have been made and, with the exception of those redactions, every document submitted in Digital Form or scanned PDF format is an exact copy of the written document filed with the Clerk, and

(2) the digital submissions have been scanned for viruses with the most recent version of a commercial virus scanning program - VIPRE version 5.0.4464, and according to the program, are free of viruses.

/s/Kathryn Brack Morrow
Kathryn Brack Morrow
BUDD-FALEN LAW OFFICES, LLC

CERTIFICATE OF SERVICE

I, Kathryn Brack Morrow, hereby certify that on September 27, 2013, I filed the foregoing Defendant-Intervenors' Consolidated Brief in Support of Agency Action with the Clerk of Court using the CM/ECF system which will provide notification of such filing to all counsel of record.

/s/Kathryn Brack Morrow
Kathryn Brack Morrow
BUDD-FALEN LAW OFFICES, LLC