UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

RISE FOR ANIMALS, et al. Plaintiffs, v. ELIZABETH GOLDENTYER, et al. Defendants.	Civ. No. 20-2004 Honorable George Jarrod Hazel ORAL ARGUMENT REQUESTED

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case challenges a decision by the United States Department of Agriculture ("USDA") to deny a Rulemaking Petition by Plaintiffs Rise for Animals ("Rise") and Animal Legal Defense Fund ("ALDF"), requesting the agency to substantially improve the standard to "promote the psychological well-being" of primates used in research that is mandated by the Animal Welfare Act ("AWA"), 7 U.S.C. § 2143(a)(2)(B). The Petition sought to build on a decision by the National Institutes for Health ("NIH") that better enrichment standards were needed for chimpanzees—one of many primates maintained by research labs.

In their opening brief, Plaintiffs demonstrated that the agency's decision to deny the Petition was arbitrary and capricious and an abuse of discretion within the meaning of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A), because in its denial decision the agency falsely asserted that, during their annual inspections, the inspectors "examine and document *all areas of care and treatment that are covered under the AWA*, including the [enrichment] plan," and the inspector "also *observes the regulated animals*; inspects the facilities, including enclosure or housing materials[,] space, and records." Denial Letter, AR 496 (emphasis added). In fact, the Administrative Record shows that, as of February 2019, the agency has actually *prohibited* its inspectors from conducting full annual inspections of labs that are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)—an industry dominated certification group. Hence, Plaintiffs demonstrated that the agency's reasoning in its denial decision is arbitrary and capricious because it "runs counter to the evidence" that was before the agency when it made that decision. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut.*, 463 U.S. 29, 43 (1983).

Plaintiffs further demonstrated that the agency's decision was deficient because it relied on non-binding "suggestions" about measures that laboratories could undertake to promote the

psychological well-being of primates; ignored decades of scientific evidence concerning the psychological needs of primates; and failed to address any of the many comments that were submitted in support of the petition, as well as the fact that the agency's sister agency—NIH—had obviously determined that the current AWA standard was not sufficient to address the psychological needs of at least one primate species.

In response, the USDA has (a) misstated the scope of the Court's judicial review; (b) relied on an impermissible *post hoc* Declaration in an attempt to explain away its patently incorrect statement about the scope of the annual inspections conducted at research laboratories; and (c) insisted that it need not address the extensive scientific literature that has been published since the current regulation was issued in 1991, or the thousands of comments urging the government to grant the Petition, nor discuss the significance of the fact that NIH obviously did not believe that the USDA's standard was adequate to promote the psychological well-being of chimpanzees. As demonstrated below, none of these arguments has any merit.

ARGUMENT

I. THIS COURT MUST REVIEW THE AGENCY'S DENIAL OF PLAINTIFFS' RULEMAKING PETITION UNDER THE ARBITRARY AND CAPRICIOUS STANDARD OF REVIEW.

Defendants wrongly insist that the *State Farm* factors governing judicial review under the arbitrary and capricious standard, 5 U.S.C. § 706(2)(A), are "the wrong standard of review." Defendants' Summary Judgment Memorandum ("Def. SJ Mem.") at 19. It is true that when reviewing an agency's decision to deny a rulemaking petition, the Court should apply the "high end" of deference to the agency's reasoning. *American Horse Protection Ass'n v. Lyng*, 812 F.2d 1, 4 (D.C. Cir. 1987). However, this by no means negates the applicability of the *State Farm* factors, which hold that an agency's decision is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important

aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency . . .” *State Farm*, 463 U.S. at 43.

Indeed, in *Lyng*—which also involved judicial review of an agency’s decision to deny a rulemaking petition—the D.C. Circuit explained that it “must consider whether the agency’s decisionmaking was ‘reasoned,’” and further stressed that the court “must assure itself that the agency considered the relevant factors, that it explained the ‘facts and policy concerns’ relied on, and that *the facts have some basis in the record*.” *Lyng,* 812 F.2d at 5 (citing *Pro. Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1220–21 (D.C. Cir. 1983)) (emphasis added). This same standard is repeated in the two cases cited by Defendants, Def. SJ. Mem. at 20—*Flyers Rts. Educ. Fund, Inc. v. FAA*, 864 F.3d 738, 743 (D.C. Cir. 2017) and *Wildearth Guardians v. EPA*, 751 F.3d 649, 653 (D.C. Cir. 2014). *See also Massachusetts v. EPA*, 549 U.S. 497, 528 (2007) (applying the arbitrary and capricious standard to review the EPA’s denial of a rulemaking petition to regulate greenhouse gases).

Plaintiffs certainly understand *why* the USDA does not want this standard of review to apply here, particularly when one of the agency’s main reasons for denying Plaintiffs’ Rulemaking Petition is completely *contradicted by the record* —i.e., that the agency already does full inspections of all of the animals at each research lab, as well as the lab’s environmental enrichment plan, to ensure that the primates’ psychological needs are being met. However, the Court may not ignore this clearly applicable standard.

II. IN CONDUCTING ITS REVIEW OF THE AGENCY'S DECISION, THE COURT MAY NOT RELY ON THE AGENCY'S *POST HOC* DECLARATION.

A. Plaintiffs Demonstrated That the Agency's Denial Decision Was Based on Inaccurate Information.

As Plaintiffs explained in their opening brief, the Animal Welfare Act specifically provides that, with respect to research facilities, "[t]he Secretary *shall inspect each research facility at least once each year and, in the case of deficiencies or deviations from the standards promulgated under this chapter, shall conduct such follow-up inspections as may be necessary until all deficiencies or deviations from such standards are corrected*." 7 U.S.C. § 2146(a) (emphasis added). Thus, the statute makes clear that the whole purpose of the mandated annual inspection is to *ensure* that each facility is operating in compliance with *all applicable AWA standards*, and that, if not, the facility is required to make necessary corrections to bring itself into compliance. *Id.*

As Plaintiffs further explained, Plaintiffs' Summary Judgment Memorandum ("Pl. SJ Mem.) at 16, when the USDA denied Plaintiffs' Petition for Rulemaking, the agency stated that the requested change to the regulation was not necessary because "APHIS [Animal Plant and Health Inspection Service] inspectors *evaluate a facilities' [sic] compliance with the regulation during the inspection*." Denial Letter, AR 496 (emphasis added). The agency further elaborated on precisely how the inspectors' evaluation is conducted. It explained that:

> [t]hey *examine and document all areas of care and treatment* that are covered under the AWA, including the [enrichment] plan. The inspector also *observes the regulated animals*; inspects the facilities, including enclosure or housing materials[,] space, and records.

Id. (emphasis added). The agency further stated that "[i]f the inspector observes that the facility is not in *full compliance* with the AWA requirements, he or she will explain *all deficiencies* and appropriately document the findings." *Id.* (emphasis added).

However, as Plaintiffs further demonstrated, we now know, based on records received after filing a related Freedom of Information Act ("FOIA") suit against the USDA, that this statement simply is not accurate with respect to research facilities that are accredited by AAALAC—an industry dominated organization—which includes the *majority of research facilities in this country*. *See* Pl. SJ. Mem. at 21. Thus, as Plaintiffs demonstrated, pursuant to an undisclosed change in the agency's inspection policies that occurred sometime in February 2019 with respect to such labs, inspectors are ***prohibited*** from conducting full inspections during the annual inspections required by the AWA, unless such an inspection is requested by the regulated facility itself. AR 3648–49. Instead, unless a full inspection is requested, the inspectors may only inspect *either* (1) the animals; (2) the facility; (3) the paperwork; *or* (4) a sample of one of more of these three categories. *See* Pl. Ex. I; AR 3646–49. Moreover, in another document obtained through the FOIA action, the agency emphasized to its inspectors that this extremely limited inspection "*counts as the facility's annual inspection*" required by the AWA. AR 3645 (emphasis added).[1]

Therefore, contrary to what the USDA told Plaintiffs when it denied their Rulemaking Petition, when they conduct the annual inspections required by the statute, USDA inspectors do *not* "evaluate" whether these facilities are in "compliance" with *all* AWA standards, nor do they "*examine* and document *all areas of care and treatment that are covered under the AWA, including the [enrichment] plan*" intended to promote the psychological well-being of primates.

[1] This particular sentence in the document was originally redacted by the agency, which claimed that this information was exempt from disclosure under Exemption 7(E) of FOIA, which protects law enforcement records to the extent that they would "disclose techniques and procedures for law enforcement investigations or prosecutions." 5 U.S.C. § 552(b)(7)(E). *See* Pl. Ex. N. However, after Plaintiffs challenged that redaction in the FOIA case, the government released the document without the redacted information.

Denial Letter, AR 496 (emphasis added). In fact, as made clear by the agency's secretly implemented AAALAC-inspection policy, the inspector is *prohibited* from examining the enrichment plans if he/she chooses to inspect one of the *other* categories covered by the policy. Indeed, under this policy, the inspectors are instructed to *rotate* what they examine every three years. AR 3647. Accordingly, if an inspector chooses in year one to examine *other* aspects of the facility, *or* the animals, *or* a sample of one or both of those categories, three to four years can go by before the inspector ever looks at the facility's enrichment plan.

Similarly, because this policy prohibits an inspector from looking at *any* animals if he/she chooses instead to examine paperwork, or some other aspect of the facility, four years can lapse before the inspector looks at a *single animal*. And, if the inspector chooses to look at the enrichment plan, he/she is then *prohibited* from also inspecting any of the animals. Therefore, in addition to the fact that this policy completly undermines the basis for the agency's petition denial, it also shows that the agency has nothing in place to ensure that whatever enrichment plan is employed by a particular facility is actually promoting the psychological well-being of the animals that are supposed to be the beneficiaries of those plans.

In any event—and there are many other reasons this policy undermines the agency's ability to enforce the AWA—the existence of this policy demonstrates that one of the principal bases upon which the USDA denied Plaintiffs' Rulemaking Petition "runs counter" to what the record actually shows occurs at the inspection of an AAALAC-accredited lab. *State Farm*, 463 U.S. at 43. Although in its *post hoc* Declaration the agency also now asserts that AAALAC accreditation is only *one* factor the agency considers when performing these limited inspections, Goldentyer Dec. ¶ 15; Def. SJ Mem. at 22, the upshot is the same—i.e., the agency is still not

conducting full inspections of each research facility as required by the AWA, 7 U.S.C. § 2146(a).[2]

B. The USDA Has Submitted an Extra-Record Declaration to Explain What it "Meant to Convey" When it Denied Plaintiffs' Rulemaking Petition.

In its attempt to counter this extremely critical point, the USDA has now submitted a *post hoc* Declaration from Defendant Elizabeth Goldentyer, Deputy Administrator for Animal Care, who signed the Petition denial, to explain what she "meant to convey" when she made the statements in the denial letter quoted above. *See* Goldentyer Dec. ¶¶ 21–23. Thus, Dr. Goldentyer now asserts that when she stated in the denial letter that USDA inspectors "examine and document *all areas of care and treatment* that are covered under the AWA," including the enrichment plan, she did not "intend" to suggest that this means that inspectors "would look at *every area of care and treatment* regulated by the Animal Welfare Act" when they conduct the annual inspections required by the statute. Goldentyer Dec. ¶ 21 (emphasis added). Dr. Goldentyer also now concedes that "for regulated entities that are required to develop, document, and follow an enrichment enhancement 'plan' for nonhuman primates pursuant to 9 C.F.R. § 3.81, the 'plan' *may not be examined*" during those inspections. Goldentyer Dec. ¶ 21 (emphasis added).

Although Dr. Goldentyer worded her Declaration to suggest that an inspector may not examine the plan "during a particular inspection," *id.*, the agency's own internal document that

[2] Moreover, one of the documents obtained by Plaintiffs under FOIA states that "[i]n response to concerns from inspectors about workload, to promote the consistency of our inspections for all research facilities, and to allow us to focus our inspection resources on facilities that present greater risks to animal welfare, in February 2019, we issued guidance that made it mandatory (rather than discretionary) for inspectors *to perform focused inspection at AAALAC accredited research facilities* unless the research facility requested a full inspection." AR 3645 (emphasis added). Thus, it does not state that this factor is only *one* that is taken into account—rather, it suggests that AAALAC-accreditation is the *determining* factor.

Plaintiffs obtained as a result of their FOIA case shows that the limited inspection employed by the agency for AAALAC-accredited facilities "*counts as the facility's annual inspection*," AR 3645 (emphasis added)—i.e., the one that is mandated by the AWA, and that is intended by Congress to ensure that research labs are in compliance with *all* applicable AWA standards. *See* 7 U.S.C. § 2146(a) (mandating that the Secretary "shall" inspect research facilities each year to determine if they are operating in violation of the Act, and "shall" conduct such follow-up inspections "as may be necessary until *all deficiencies and deviations* from such standards *are corrected*." (emphasis added)). Clearly, if the inspector is not even looking at the enrichment plan when he/she conducts the annual inspection, the agency cannot possibly comply with this statutory requirement.[3]

Similarly, in her *post hoc* Declaration, Defendant Goldentyer now asserts that although she stated in the denial letter that "[t]he inspector also *observes the regulated animals*," during the annual inspection, she did not "mean" that "the USDA inspector would inspect all of those regulated aspects." Goldentyer Dec. ¶ 22 (emphasis added). Rather, she "meant to convey" that the "overall USDA inspection process"—including the fact that the agency does *not* conduct full inspections of AAALAC-accredited facilities—was "designed" to ensure that the animals are treated in accordance with the requirements of the AWA. *Id.* However, if the inspector is not looking at a single animal—which the inspector is ***prohibited from doing*** if the lab is AAALAC-

[3] In her Declaration Dr. Goldentyer suggests that the agency could provide more information to the Court about the other criteria employed by the agency for these "focused" inspections, "on an *ex parte basis*, and under seal." Goldentyer Dec. at 5, n. 2. However, according to the internal agency documents Plaintiffs obtained through their FOIA case, although the details of the inspection policy were not to be *publicly* disclosed, they were to "be conveyed by the inspectors *to their facilities*." AR 3649 (emphasis added). Thus, because the regulated industry apparently already knows the criteria that the agency uses, there should be no reason why this information would have to be presented to the court either *ex parte* or under seal.

accredited and the inspector has chosen to examine one of the *other* aspects of the facility—it defies reality that the inspector is somehow nevertheless determining that *all of the animals are being treated in compliance with the facility's psychological enrichment plan*. *See also, e.g.,* Rulemaking Petition at 30, AR 033 (explaining that if "behavioral manifestations of clearly defined indicators of psychosocial stress [] indicate that an individual primate is suffering, an appropriate intervention must be required. If that intervention fails to result in a meaningful amelioration of symptoms so that the animal can live in a state of psychosocial equilibrium, the primate must be sent to a sanctuary for psychological rehabilitation."); Comments of the Laboratory Primate Advocacy Group, Pl. Ex. B, at 3 (stressing that a successful environmental enrichment plan can only be demonstrated "*by an absence or reduction of behaviors symptomatic of stress and trauma*") (emphasis added). Indeed, as Judge Xinis of this Court observed in a case involving inadequate veterinary care for animals at a zoo, waiting even a year and a half to actually observe the animals is "grossly inadequate." *PETA v. Tri-State Zoological Park of Western Md*., 424 F.Supp.3d 404, 413 (D. Md. 2019).

And, because under the agency's inspection policy the inspectors are *prohibited* from inspecting *both* the enrichment plan *and* the animals during one of these inspections—i.e., they must choose one or the other—there simply is no way the inspector can determine whether the animals are being treated *in compliance with that plan.*

Dr. Goldentyer also explains in her *post hoc* Declaration that when she stated in the denial letter that "[i]f the inspector observes that the facility is not in *full compliance with the [Animal Welfare Act]* requirements, he or she will explain *all deficiencies* and appropriately document the findings," she "did not intend" to suggest that the inspector would "determine that a facility had complied with *every aspect of the Animal Welfare Act*." Goldentyer Dec. ¶ 23

(emphasis added) (alteration in original). Rather, again, she "meant to convey" something very different—i.e., that an inspector would only take such action if he or she identified a particular deficiency during one of these very limited inspections. *Id.*

C. It is Well Settled that Such *Post Hoc* Declarations are Impermissible.

As the foregoing demonstrates, the USDA has submitted the Declaration of Defendant Goldentyer to explain that, although she informed Plaintiffs that the agency was denying their Rulemaking Petition because its inspectors already annually inspect *all* of the animals and *all* of the enrichment plans, along with all of the other requirements of the AWA, in fact, the *opposite* is true. Under the AAALAC inspection policy, the inspectors do *not* look at all of the animals, enrichment plans, and other aspects of the facility to ensure that the lab is in compliance with all AWA standards. In fact, we now know from the policy itself that the inspectors are *prohibited* from doing so unless requested by the regulated facility itself. AR 3648–49.

No matter how hard the USDA tries to reconcile the patent inaccuracies of the statements made in its denial of Plaintiffs' Rulemaking Petition with the AAALAC inspection policy in the Administrative Record, this Court may not consider such *post hoc* rationalizations. Rather, as the Supreme Court recently reiterated, "*[a]n agency must defend its actions based on the reasons it gave when it acted*," *Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020) (emphasis added)—not with *post hoc* declarations explaining what the agency "meant" to say. *See also American Textile Mfrs. Institute, Inc. v. Donovan,* 452 U.S. 490, 539 (1981) ("[T]he *post hoc* rationalizations of the agency . . . cannot serve as a sufficient predicate for agency action."); *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419 (1971) (rejecting "litigation affidavits" from agency officials as "merely post hoc rationalizations").

The Court of Appeals for this Circuit has assiduously applied this well settled tenet of administrative law. *See, e.g., Appalachian Voices v. United States Dep't of Interior*, 25 F.4th 259, 274 (4th Cir. 2022) (rejecting a Fish and Wildlife Service argument that "isn't found anywhere in the record" as an "impermissible post hoc rationalization"); *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.,* 707 F.3d 462, 467–68 (4th Cir. 2013) ("[A] reviewing court may look only to [] *contemporaneous* justifications in reviewing the agency action.") (emphasis in original); *N.C. Wildlife Fed'n v. N.C. Dep't of Transp*., 677 F.3d 596, 604 (4th Cir. 2012) ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself," and the "'basis articulated by the agency' is the administrative record, *not subsequent litigation rationalizations*." (quoting *State Farm,* 463 U.S. at 50) (emphasis added).

Defendants' self-serving attempt to convince the Court to accept its blatant *post hoc* rationalizations as mere "background information," Def. SJ Mem. at 20 n. 5, is "as silly as it sounds." *Public Citizen v. Steed*, 733 F.2d 93, 102 (D.C. Cir. 1984). Dr. Goldentyer's Declaration states ***the opposite*** of what the agency told Plaintiffs when it denied their Rulemaking Petition—i.e., rather than inspecting all of the animals and all of the enrichment plans and making sure the animals are receiving the psychological enrichment mandated by the AWA, the inspectors are *prohibited* from observing *all* of the animals and *all* of the enrichment plans when they conduct their annual inspections if the facility is accredited by AAALAC.

Accordingly, as Plaintiffs explained in their opening brief, because the agency's explanation for its denial of the Petition—as actually *stated* in that decision document—is completely *contrary* to what, in fact, is actually entailed in these inspections, the USDA's denial of Plaintiffs' Petition is a textbook example of an arbitrary and capricious decision. *State Farm,* 463 U.S. at 43 (an agency's decision is arbitrary and capricious if the agency has "offered an

explanation for its decision that *runs counter to the evidence before the agency*") (emphasis added). The agency's protestation that the statements in the denial letter do not run afoul of this standard "[i]n light of the *additional context* provided in the Goldentyer Declaration," Def. SJ Mem. at 24 (emphasis added), only highlights the impermissibility of relying on this *post hoc* Declaration. Thus, Defendants are telling the Court that it cannot base its decision on what the agency *actually* said in its decision document, but instead should decide whether its decision was arbitrary and capricious based on what the agency "meant" to say, as now explained in the Goldentyer Declaration. However, because the Court may not help the agency re-write its decision document, this effort on the part of the agency must fail. As the Supreme Court long ago emphasized, "[t]he reviewing court should not attempt itself to make up for such deficiencies: 'We may not supply a reasoned basis for the agency's action that the agency itself has not given." *State Farm*, 463 U.S. at 43 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947).

D. AAALAC Accreditation Does Not Mean a Facility is in Compliance with the AWA.

Plaintiffs agree with the agency that the lawfulness of the AAALAC Inspection Policy is not presently before the Court and will be decided in the related case. Def. SJ Mem. at 22, n.7; *Rise for Animals v. Vilsack*, Civ. No. 8:22-cv-00810. However, because the agency has tried mightily to obscure the nature and scope of its inspections with its *post-hoc* Declaration, it is important for the Court to know a few significant facts about AAALAC accreditation.

First, as mentioned above, AAALAC is an industry-dominated organization that charges research labs hefty fees to receive its accreditation. PETA Comments, AR 5770 (facilities spanning 100,000 square feet to 199,999 square feet must pay an initial application fee of $12,240 and an annual fee of $8,280) (citing https://www.aaalac.org/accreditation/fees.cfm.).

Indeed, because AAALAC is an industry-based organization, when Congress originally enacted the AWA in 1966 it specifically rejected the suggestion that authority to determine compliance with the standards be given to AAALAC, due to what one of the statute's sponsors described as "the shocking failure of self-policing by the medical community." 112 Cong. Rec. 13,893 (1966) (Statement of Senator Monroney). As Senator Monroney explained, deferring to AAALAC "seems hardly adequate to the problem, especially since *the inspectors would be drawn from the same scientific community involved in being inspected, a situation where there would be no serious impartiality*." *Id.* (emphasis added); *see also Animal Welfare Act: Hearing on S. 2322, S. 3059, and S. 3138 Before the S. Comm. on Commerce,* 89th Cong. 263 (1966) (statement of Senator Monroney) (noting that AAALAC is "part of the same professional group that today is in charge of the research facilities of most of the research agencies in our various medical schools"). *See also* PETA Comments, AR 5769 (urging the USDA not to defer to AAALAC-accreditation because "[f]irst and foremost, AAALAC is an industry-dominated organization).[4]

Indeed, as Senator Joseph Clark explained in rejecting the suggestion that Congress defer to AAALAC, "I never saw a situation more inclined to the cliche that you are setting a *fox to watch the chicken coop*." *Animal Welfare Act: Hearing on S. 2322, S. 3059, and S. 3138 Before the S. Comm. on Commerce,* 89th Cong. 263 (1966) (statement of Senator Clark) (emphasis added). He further described AAALAC as operating a "self-policing coverup of conditions in experimental

[4] The comments cited here were submitted to the USDA in conjunction with a different, but related matter –i.e., the USDA's 2018 proposal to "recogniz[e] the use of third-party inspection and certification programs when determining APHIS inspection frequencies at facilities licensed or registered under the Animal Welfare Act." 83 Fed. Reg. 2959, 2959 (January 22, 2018). Therefore, as Plaintiffs will demonstrate in their related case challenging the legality of this inspection policy, the USDA actually solicited comment from the public on this issue. *Id.*

laboratories." *Id.* Thus, when drafting the language of § 2146(a) that mandated an annual inspection of each research lab, Congress made absolutely clear that "these inspectors *will be employees of the U.S. Department of Agriculture"* – not AAALAC. H.R. Rep. No. 89-1848, at 13 (1966) (Conf. Rep.) (emphasis added) .

Second, during AAALAC's site "visits" to determine accreditation—which the organization only conducts once every *three years*—AAALAC does not even determine whether the facility is in compliance with all AWA standards, PETA Comments, AR 5770, nor report its findings to the USDA. Thus, even when AAALAC conducts one of these "visits"–which are all *announced to the facilities in advance,* AR 5770 —it is not determining whether the facility is or is not in compliance with all AWA standards.

Third, as the USDA well knows, many facilities have been found to be operating *in violation of the AWA, despite the fact that they are accredited by AAALAC*. Indeed, as one peer-reviewed article pointed out, an analysis of AAALAC-accredited facilities revealed that they were "frequently cited for AWA noncompliance items," and that, when compared to non-AAALAC accredited facilities, "AAALAC-accredited sites had *significantly more AWA [noncompliant items] on average* compared with nonaccredited sites," and also had "more [non-compliance items] related to improper veterinary care, personnel qualifications, and animal husbandry." Goodman, et al., *Does Accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) Ensure Greater Compliance With Animal Welfare Laws?*, J. Applied Animal Welfare Science 1 (2015), AR 6196. (emphasis added); *see also* PETA Comments, AR 5771–74, (describing in detail numerous AWA violations by AAALAC-accredited labs).

Therefore, the notion that deference to AAALAC-accreditation somehow fulfills the agency's mandate under the AWA to "inspect each research facility at least once each year" and to determine and ensure correction of all "deficiencies and deviations" from applicable AWA standards, 7 U.S.C. § 2146(a), is wishful thinking at best on the part of the agency. Plaintiffs intend to demonstrate to the Court in the related pending case, *Rise for Animals v. Vilsack*, Civ. No. 8:22-cv-00810, that this inspection policy violates both the plain language and clear intent of Congress.[5]

III. NONE OF DEFENDANTS' OTHER ARGUMENTS HAVE ANY MERIT.

Defendants make several additional arguments in their brief—none of which have any merit.

A. The Mere Fact That Inspectors Cite Facilities for Violations of the Primate Regulation Does Not Mean the Regulation Need Not Be Updated to Ensure the Psychological Well-being of Primates.

As it did in its denial letter, the USDA continues to rely on the fact that the agency has issued citations for violations of the 1991 regulation over the years, insisting that this "negates Plaintiffs' argument that Section 3.81 is too vague to be enforceable." Def. SJ Mem. at 27, n. 9. However, the mere fact that the agency has issued citations for violations of the current standard does not mean that this amorphous standard is any more enforceable than it was in 1999 when

[5] While Plaintiffs believe that it is clear the Court may not rely on Dr. Goldentyer's extra-record Declaration here, to the extent the Court may nevertheless decide to do so, that Declaration raises far more questions than it resolves concerning the basis for the agency's decision to deny Plaintiffs' Rulemaking Petition, including murky language about *which* inspections the agency is even referring to in the Declaration –e.g. the annual inspections required by Section 2146(a) of the AWA, or some other inspections. *See, e.g.*, Goldentyer Dec. at ¶ 21 (stating that "Thus, for regulated entities that are required to develop, document, and follow an environment enhancement 'plan' for nonhuman primates . . . the 'plan' may not be examined during a *particular inspection*.") (emphasis added). Accordingly, should the Court decide to consider this Declaration, Plaintiffs would need the opportunity to take discovery regarding the statements contained therein to further demonstrate to the Court that the agency has acted arbitrarily and capriciously here. *See* Fed. R. Civ. P. 56(d)(2); Declaration of Ed Butler, Pl. Ex. O.

the agency informed the public that it was issuing a Draft Policy with far more specific requirements because its own inspectors "requested information and clarification on *how to judge whether someone was meeting the requirements in § 3.81*." 64 Fed. Reg. 38145, 38146 (July 15, 1999), AR 076 (emphasis added). Indeed, at that point in time, the agency acknowledged that the Draft Policy was "necessary" to demonstrate what is required to satisfy the standard. *Id.*

In fact, at the time the 1999 Draft Policy was issued, USDA inspectors had also been issuing citations for violations of the standard, although they also believed that it was vague and difficult to enforce. Indeed, the 1999 Draft Policy that would have required far more concrete and enforceable standards—but which was never finalized the agency—was based on a 1996 USDA Report the agency prepared concerning the experience of its inspectors in enforcing the standard. *See* 64 Fed. Reg. at 38146, AR 076 (explaining that "[i]n 1996, after 5 years of experience enforcing § 3.81, we evaluated the effectiveness of the performance standards by surveying our inspectors about their experience in reviewing environment enhancement plans developed under § 3.81."). That Report, excerpts of which are attached as Pl. Ex. P, shows that even though the inspectors believed the standard was difficult to enforce, they were nevertheless issuing citations for what they *believed* might be deviations. *See, e.g., id.* at H-1 (stating "what the inspectors do in general and criteria they use for evaluating the performance plans); *id.* at H-2 (several inspectors explaining that "[i]f I do not see any types of 'toys'/'apparatus' within the enclosure I will write it up").[6]

[6] Because this is an official USDA Report, the Court may take judicial notice of its contents. *See, e.g., United States v. DOE*, 962 F.3d 139, 147, n. 6 (4th Cir. 2020) ("we may take judicial notice of government reports").

However, this did not dissuade the agency from concluding that more was "necessary" to demonstrate to inspectors and the general public the specific measures that were actually required to promote the psychological well-being of primates. 64 Fed. Reg. at 38146, AR 076. And, as Plaintiffs also demonstrated both in their Rulemaking Petition and in their opening brief, obviously NIH concluded in 2013 that much more was required to promote the psychological well-being of chimpanzees. *See* Rulemaking Petition, AR 022, 035; Pl. SJ Mem. at 27–29.

B. The USDA Failed to Grapple with the Fact that NIH Concluded that the USDA's Existing Standard was Inadequate.

Nor is there any merit to Defendants' position that Plaintiffs somehow waived their argument that the agency acted arbitrarily and capriciously and abused its discretion by failing to address the fact that its own sister agency, NIH, had obviously concluded that the USDA's 1991 standard was sorely deficient with respect to promoting the psychological well-being of chimpanzees—the only species NIH studied. *See* Pl. SJ Mem. at 27–29; Def. SJ Mem. at 30–32. As reflected in the Rulemaking Petition itself, the whole impetus for the Petition was the fact that NIH had concluded that more specific requirements were needed to ensure that chimpanzees received the environmental enrichment they need. *See* Petition at 3-4, AR 006–07 ("The new NIH recommendations are based on scientific evidence and expertise from some of the world's leading experts on chimpanzee well-being. These recommendations present a substantiated and clear definition of key components of what is minimally necessary to promote the psychological well-being for primates – i.e. environmental enhancement, access to the outdoors, and opportunities for choice and self-determination. With this Petition, ***we urge the USDA to adopt these same, species appropriate standards as the "minimum requirements" for a "physical environment adequate to promote the psychological well-being" of all primates used in research***. (7 U.S.C. § 2143(a)(2)(B) (emphasis in original)). Indeed, Defendants concede that

this was the overall purpose of the Petition. *See* Def. SJ Mem. at 32 ("Plaintiffs' petition *specifically asked that the USDA adopt the NIH's recommendations* for chimpanzees and to adopt similar regulations for other species of primates") (emphasis added).

While it is true that Plaintiffs did not specifically spell out the fact that research facilities subject to the NIH's additional requirements were *already* covered by the USDA's existing AWA primate regulation, surely the USDA knows this unassailable fact, made quite clear by the AWA itself. *See* 7 U.S.C. § 2136 ("[e]very research facility . . . shall register with the Secretary"); *id.* § 2143(a)(1) ("[t]he Secretary shall promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, *research facilities*, and exhibitors") (emphasis added); *id.* § 2143(a)(2) (such standards "shall include minimum requirements . . . for a physical environment adequate to promote the psychological well-being of primates."); *id.* § 2143(a)(7)(A) ("The Secretary shall require *each research facility* to show upon inspection, and to report at least annually, that the provisions of this chapter are being followed") (emphasis added). In fact, the NIH's own Policy makes clear that, in addition to whatever supplemental standards an institution may adopt for its animal care program, "[*c*]*ompliance with applicable USDA regulations is an absolute requirement*". *See* Public Health Service Policy on Humane Care and Use of Laboratory Animals, Pl. Ex. A, at 9 n.2 (emphasis added). [7]

[7] Furthermore, in their Petition, at 19, AR 022, Plaintiffs relied heavily on a report by the Working Group of NIH's Council of Councils, which makes specific reference to "the applicability of existing standards set forth by the Animal Welfare Act" and the fact that the USDA is "the agency charged with federal oversight." Council of Councils Working Group on the Use of Chimpanzees in NIH-Supported Research Report at 65, AR 1995.

The Court of Appeals for this Circuit has explained that an argument is not waived if the relevant issue was "sufficiently raised" *Mayor of Baltimore v. Azar*, 973 F.3d 258, 290 (4th Cir. 2020), and that an issue is "sufficiently raised" even if it was raised "generally" or referenced "implicitly." *1000 Friends of Maryland v. Browner*, 265 F.3d 216, 228 (4th Cir. 2001). As the Court of Appeals has explained, the purpose of this requirement is to ensure that the agency has "an opportunity to consider the matter." *Id.* Therefore, because the *entire premise* of Plaintiffs' Rulemaking Petition was to urge the USDA to follow NIH's lead and update the psychological well-being standard for *all* primate species, it is disingenuous in the extreme for the agency to now insist that it had no opportunity to address the fact that NIH had concluded that much more was needed to ensure the psychological well-being of chimpanzees than was provided by the USDA's existing AWA standard.

The agency's assertion that it nevertheless *did* address this matter by explaining why its current—*thirty-year-old*—regulation was sufficient, Def. SJ Mem. at 32, also makes no sense. In fact, in its denial letter the agency attempted to demonstrate that all of the NIH's new requirements for the environmental enrichment of chimpanzees are already *subsumed* by the USDA's 1991 regulation. *See, e.g.,* Denial Letter, AR 496–98. However, as Plaintiffs demonstrated in their opening brief, this simply is not correct. *See* Pl. SJ Mem. at 28–29 (the USDA's denial letter states that the NIH's requirement that chimpanzees be provided with "materials to construct new nests on a daily basis" is somehow already dictated by the existing regulation that simply provides that the primates' primary enclosures must be "enriched through the provision of non-injurious means of expressing species typical behavior"). Moreover, the USDA's insistence that its psychological well-being standards already cover all of the matters dictated by NIH's requirements only serves to highlight the need for an explanation as to why

NIH believed additional requirements were needed. The USDA's failure to address this extremely salient point demonstrates that the agency "failed to consider an important aspect of the problem"—a hallmark of arbitrary and capricious decisionmaking. *State Farm*, 463 U.S. at 43.

C. The USDA Failed to Address Voluminous Scientific and Other Evidence in the Record Demonstrating a Need to Update the 1991 Standard.

As Plaintiffs demonstrated in their opening brief, in its denial decision the USDA also failed to address the extensive scientific and other expert evidence submitted to it as part of the Rulemaking Petition and in the numerous public comments urging its adoption. Pl. SJ Mem. at 24–27. In response, the agency contends that the standard of review for the denial of a rulemaking petition does not require an examination of whether the agency responded to the evidence submitted to it in support of the petition. Def. SJ Mem. at 29. However, this also is not correct.

Regardless of what prompts an agency to make a decision that is judicially reviewable—as the USDA's denial decision is—it is axiomatic that the agency must consider all "relevant factors." *See, e.g.*, *Pro. Drivers*, 706 F.2d at 1220 (in reviewing agency's decision denying petition to amend regulation, "[t]he court's task is to discern *whether the relevant factors were considered* and whether the ultimate decision reflects reasoned decision-making") (emphasis added); *Lyng*, 812 F.2d at 5 (in reviewing an agency decision to deny a rulemaking petition "the court *must assure itself that the agency considered the relevant factors*") (citing *Pro. Drivers*, 706 F. 2d at 1220–21) (emphasis added).

Here, Plaintiffs' Rulemaking Petition sought to have the agency revisit an almost 30-year-old regulation intended to satisfy the mandate of the AWA that the agency promulgate a standard that is "adequate to promote the psychological well-being of primates," 7 U.S.C. § 2143(2)(B).

Plaintiffs' Petition not only included decades of scientific literature issued since 1991 about the psychological needs of primates, but also relied heavily on a more recent decision by NIH to substantially improve the standards that apply to chimpanzees. Thus, the agency had an obligation to at least address this clearly relevant information.

Contrary to Defendants' position, the agency was also required to consider and address at least *some* of the thousands of comments that were submitted in support of the Petition. *See* AR 495 (APHIS received a total of 10,137 comments on Plaintiffs' Petition; the agency reported that 7232 comments (71%) were in favor of the Petition; 63 comments (1%) opposed granting the Petition; and 2842 comments (28%) did not address the Petition). Indeed, when it first received Plaintiffs' Petition, the USDA responded by noting that because the Petition raised issues that "*are important and that many parties will have an interest in*," the agency had decided to publish the Petition in the Federal Register for public comment. USDA Initial Response to Plaintiffs' Petition, AR 491 (emphasis added). The agency also told Plaintiffs that it would render a final decision on their Petition once it had "analyzed all of the comments." *Id.* Moreover, when the agency published the Petition in the Federal Register and solicited public comment on whether it should be granted, the agency informed the public that "[w]e are making this petition available to the public and soliciting comments regarding the petition and any issues raised by the petition *that we should take into account as we consider this petition*." 80 Fed. Reg. 24840, 24840 (May 1, 2015), AR 492 (emphasis added).

As the D.C. Circuit long ago explained, "the opportunity to comment is meaningless unless the agency responds to significant points raised by the public." *Home Box Office v. FCC*, 567 F.2d 9, 35–36 (D. C. Cir. 1977). Here, the agency not only told the public it would take comments "into account" in making its decision, but, based on that representation, it received over 7,000 comments in support of the Petition. Denial Letter, AR 495. Yet, like its failure to

respond to any of the voluminous scientific evidence submitted by Plaintiffs in support of their Petition, the agency failed to respond to *any* of these comments. Particularly given this record, the USDA's position that it is not required to respond to any of the comments simply cannot be sustained, as it shows that the agency utterly failed to consider the requisite "relevant factors"—i.e. (1) that the current regulation was inadequate, *see* Petition at 10–18, AR 013–21; *see also* Comment of Dr. Mary Lee Jensvold, Primate Behaviorist & Ecologist, Pl. Ex. Q; Comment of Amy Kerwin, Former Research Specialist, Pl. Ex. R, at 4, 21–23; Comments of the Animal Legal Defense Fund, Pl. Ex. S, at 1; Comments of People for the Ethical Treatment of Animals, Pl. Ex C; (2) that decades of scientific research and current conditions at research labs demonstrate that the current standard is not working to promote the psychological well-being of primates, *id.* at 33–42, AR 036–45; *see also* Comment of Dr. Marc Bekoff, Biologist, Pl. Ex. H; Comment of Nedim C. Buyukmihci, V.M.D., Pl. Ex. K, at 2; Comments of the Laboratory Primate Advocacy Group, Pl. Ex. B, at 1; Comments of the Animal Legal Defense Fund, Pl. Ex. S, at 4; Comments of People for the Ethical Treatment of Animals, Pl. Ex C; and (3) that more specific concrete standards are required to satisfy the AWA's requirement that the agency promulgate a standard "for a physical environment adequate to promote the psychological well-being of primates." 7 U.S.C. § 2143(a)(2)(B); Petition at 22–32, 48–49, AR 025–35, 051–52; *see also* Comment of Dr. Marc Bekoff, Biologist, Pl. Ex. H; Comment of Gloria Grow, Fauna Foundation, Pl. Ex. D; Comments of the Animal Legal Defense Fund, Pl. Ex. S, at 3; Comment of Cruelty Free International, Pl. Ex. T; Comments of People for the Ethical Treatment of

Animals, Pl. Ex C. Instead, the agency ignored *all* of the evidence and *all* of the comments and summarily asserted that it believes its current standard is sufficient. Denial Letter, AR 496.[8]

The USDA's principal argument as to why it need not respond to any of the scientific evidence concerning the need for a better standard is that the 1991 regulation requires the regulated facilities to devise enrichment plans "in accordance with the *currently accepted* professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian." Def. SJ Mem. at 29 (quoting 9 C.F.R. § 3.81) (emphasis by Defendants). However, as Plaintiffs explained, Pl. SJ Mem. at 4–5, the regulation does not even require the USDA to review and approve these plans before they are implemented, nor does the regulation require facilities to revise the plans to ensure that they are consistent with such "currently accepted" professional standards. *See* 9 C.F.R. § 3.81.

Further, as Plaintiffs have now demonstrated, under the agency's secretly implemented AAALAC inspection policy, its inspectors are *prohibited* from even *looking* at these plans for several years when they conduct their annual inspections of AAALAC-accredited labs, if they choose to examine some *other* aspect of the facility—e.g., the facility itself, the animals, or a sample of one or both factors. *See* Pl. SJ Mem. at 17–18. Therefore, putting aside the fact that the agency ignored all of the relevant scientific evidence amassed by Plaintiffs, NIH, and the public about the psychological needs of primates, there simply is no basis upon which the agency could possibly conclude that these research labs are, in fact, employing "currently accepted professional standards." *See also, e.g.*, *N.J. Soc'y for the Prevention of Cruelty to Animals v. N.J.*

[8] The one case cited by Defendants for the proposition that it was not required to respond to any of these comments, *Wildearth Guardians,* 751 F.3d at 653, Def. SJ Mem. at 29, says nothing of the kind and merely reiterates the appropriate standard of review for the denial of a rulemaking petition.

Dep't of Agric., 955 A.2d 886, 906–07 (N.J. 2008) (rejecting agency's decision to defer to the "routine husbandry practices" commonly taught in various educational institutions to comply with its obligation to exempt only "humane" agricultural practices from the state's animal cruelty statute, because the agency "*accepted, without analysis*," the practices taught in every such school "wherever they might be found around the globe.").

Accordingly, the agency's failure to respond to *any* of this extremely relevant evidence was arbitrary and capricious, and an abuse of discretion, especially when the AWA specifically commands that the agency "*consult experts,*" "other Federal departments, agencies, or instrumentalities concerned with the welfare of animals used in research," and "the Secretary of Health and Human Services," when determining appropriate AWA standards. 7 U.S.C. §§ 2143(a)(5), 2145(a).

CONCLUSION

For all of the foregoing reasons, as well as those set forth in Plaintiffs' opening brief, the Court should grant summary judgment for Plaintiffs and deny summary judgment for Defendants.

Respectfully submitted,

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