UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

SOUTHERN DIVISION

RISE FOR ANIMALS and
ANIMAL LEGAL DEFENSE FUND,

Plaintiffs,

v.

TOM VILSACK, Secretary of the United States Department of Agriculture and ELIZABETH GOLDENTYER, Deputy Administrator of Animal Care,

Defendants.

Civil Action No.

COMPLAINT FOR DECLARATORY RELIEF AND VACATUR

INTRODUCTION

1. Plaintiffs, two animal protection organizations, challenge a policy secretly implemented by the Animal and Plant Health Inspection Service ("APHIS"), a division of the United States Department of Agriculture ("USDA"), under which the agency relies on third-party accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care ("AAALAC"), a private trade association, to evade its statutory obligation to conduct full annual inspections of research facilities as required under the Animal Welfare Act ("AWA"), 7 U.S.C. § 2146. By deferring to a third-party accreditor under this policy (hereinafter "Partial Inspection Policy"), the agency contravened its statutory duties under the AWA to conduct full inspections of research facilities each year, ignored public opposition to incorporating third-party accreditation into its decision of how and when to inspect research facilities, and abandoned prior agency practice without providing a reasoned basis for doing so in violation of the Administrative Procedure Act, 5 U.S.C. § 551 et seq. As a result of APHIS's

actions, animals used in laboratory research at AAALAC accredited facilities—the overwhelming majority of major research facilities covered by the AWA—are now deprived of the AWA's minimum safeguards against inhumane treatment.

2. This Partial Inspection Policy violates the plain language of the AWA, which provides that the USDA "*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 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).

3. The Partial Inspection Policy also constitutes an improper delegation of the USDA's statutory obligation to a non-governmental entity that is funded by the very facilities the USDA is charged with inspecting to ensure compliance with all applicable AWA standards. Accordingly, the Partial Inspection Policy is "arbitrary and capricious," an "abuse of discretion," and "not in accordance with law" within the meaning of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2).

4. Similarly, the new Partial Inspection Policy was issued despite overwhelming public opposition and evidence demonstrating that reliance on third-party accreditation as a basis for not conducting a full inspection of each research facility would result in far less protection of animals used in research. Because the agency revised its inspection policy contrary to overwhelming evidence and without any reasoned explanation, the agency's issuance of the Partial Inspection Policy was also arbitrary and capricious and an abuse of discretion within the meaning of the APA.

JURISDICTION

5. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 2201 (2018).

PARTIES

6. Plaintiff Rise for Animals ("Rise") is a nonprofit, tax-exempt 501(c)(3) organization whose mission is to reduce animal suffering. Rise seeks to end unnecessary animal experimentation, to promote and encourage the transfer of animals from laboratories to animal sanctuaries, and to reduce the suffering of laboratory animals. Rise also works to educate the public, lawmakers, and others about the needs of animals used in research and the suffering they endure by advocating that biomedical companies transition from animal testing to non-animal alternatives to achieve their research objectives.

7. APHIS's unlawful Partial Inspection Policy impairs Rise's mission to protect animals from inhumane treatment and to educate the public and policymakers about how animals are treated in research facilities. Because of the unlawful Partial Inspection Policy, APHIS inspectors no longer conduct full annual inspections of the vast majority of research facilities in this country, as required by the AWA. This means that the inspectors are not ascertaining if these facilities are, in fact, operating in compliance with all applicable AWA standards. As a result, the inspection reports the inspectors prepare—and that Congress requires be publicly disclosed, 7 U.S.C. § 2146a—do not contain complete information about whether these facilities are actually complying with all such standards, or whether they are operating in violation of those standards. As a result, Rise is deprived of information to which it is entitled under the AWA and that is critical to its ability to carry out its fundamental mission.

8. For example, one of Rise's most important tools for its animal advocacy work is its "Animal Research Laboratory Overview" ("ARLO") database. Rise uses ARLO to collect and publicly disseminate information about animal research facilities, including the kinds of research being conducted by these facilities, and whether such research is being conducted in compliance with all applicable state and federal laws, including the AWA. Rise heavily relies on the information contained in USDA inspection reports to update the database and maximize its effectiveness.

9. Rise also relies on APHIS inspection reports to determine how best to allocate its resources by focusing its educational and advocacy efforts on those facilities with the worst track records of AWA non-compliance.

10. Because Rise is now being deprived of this critical information as a result of the agency's unlawful Partial Inspection Policy, it must instead pursue alternative, more time-consuming and resource-intensive measures to obtain the information it needs to maintain ARLO and effectively prioritize its work. For example, Rise must now submit more Freedom of Information Act ("FOIA") requests, as well as requests under state open records laws, to obtain information about how the animals are being treated at AAALAC-accredited research facilities and whether the USDA is complying with its statutory obligation to ensure that these facilities are operating in compliance with applicable AWA standards. But even exhaustive records requests—e.g., for complaints lodged against facilities or requests by facilities for permission to use certain procedures or deviate from regulations—cannot replace full inspection reports if inspectors only perform partial inspections.

11. Rise's informational and organizational injuries will be redressed if Plaintiffs prevail in this action because, as a result, the USDA will be required to conduct *full* annual

inspections of all research facilities as required by the AWA, which in turn will provide Rise with crucial information about whether these facilities are operating in compliance with all applicable AWA standards.

12. Plaintiff Animal Legal Defense Fund ("ALDF") is a national non-profit, tax-exempt 501(c)(3) membership organization that uses the legal system to protect the lives and advance the interests of animals. ALDF accomplishes this mission by engaging in litigation, providing legal assistance and training to prosecutors, supporting strong animal protection legislation, combating legislation that is harmful to animals, and providing resources and opportunities to law students and professionals to advance the emerging field of animal law.

13. In pursuit of these activities, ALDF regularly relies on inspection reports generated as a result of the inspections of research facilities that APHIS is required to conduct pursuant to the AWA to review, monitor, assess, and inform the public about conditions at research facilities and whether the USDA is performing its statutory duties to ensure that these facilities are treating animals humanely and in compliance with all applicable standards. These inspection reports typically include information about whether a particular facility is operating in compliance, or non-compliance, with relevant AWA standards, as well as what is being done to correct any deficiencies. ALDF also relies on APHIS inspection reports to educate its members about these matters and to prioritize its advocacy efforts by focusing on those facilities that are in chronic violation of the AWA.

14. Under the Partial Inspection Policy, the USDA *prohibits* inspectors from conducting full inspections of any AAALAC-accredited facility each year. Thus, the USDA inspection reports no longer contain information that is critical to ALDF's work.

15. Without this information, ALDF is forced to pursue other time-consuming strategies to obtain information to which they are legally entitled, including submitting FOIA requests to the USDA, pursuing state public records requests for information pertaining to research facilities, and soliciting information from others about animal mistreatment and neglect at specific facilities. Still, even exhaustive records requests and independent investigations cannot replace the information provided in full inspection reports. Having to seek and obtain information from other sources consumes significantly more staff time and resources than would be required if this information were publicly available in the inspection reports that the agency is required to publicly disclose and that would contain this information but for the USDA's unlawful Partial Inspection Policy. These resources have to be diverted from other activities and projects that ALDF would otherwise pursue to further the protection of animals.

16. ALDF's injuries are directly traceable to Defendants' unlawful Inspection Policy. If the USDA conducted full annual inspections of research facilities as required by the AWA, it would necessarily generate more comprehensive reports detailing instances of non-compliance with AWA standards, and also allow ALDF to more effectively monitor what the agency is doing to bring such facilities into compliance with the AWA.

17. ALDF's injuries will be redressed if Plaintiffs prevail in this action because the USDA will be required to conduct full annual inspections as required by the AWA, allowing ALDF to once again rely on inspection reports produced through such inspections—and mandated by Congress to be publicly disclosed—to further its work ensuring AWA-regulated facilities comply with animal welfare statutes, educating the public about non-compliance at such facilities, and monitoring whether the USDA is adequately complying with its statutory duties.

18. Defendant Tom Vilsack is the Secretary of the USDA, the federal agency responsible for devising and implementing the USDA's unlawful Inspection Policy.

19. Defendant Dr. Elizabeth Goldentyer is Deputy Administrator for the USDA's Animal and Plant Health Inspection Service's ("APHIS") Animal Care program and the official responsible for devising and implementing APHIS's unlawful Partial Inspection Policy.

STATUORY AND FACTUAL BACKGROUND GIVING RISE TO PLAINTIFFS' CLAIMS FOR RELIEF

A. The Animal Welfare Act

20. Congress enacted the AWA in 1966 to "insure that animals intended for use in research facilities . . . are provided humane care and treatment." 7 U.S.C. § 2131(1). The statute was passed in response to "the shocking failure of self-policing by the medical community," 112 Cong. Rec. 13,893 (1966) (statement of Sen. Monroney), and specifically as a check on AAALAC-accreditation, which, as one Senator explained, was "setting a fox to watch the chicken coop," *id.* at 202 (statement of Sen. Clark).

21. To "insure" that animals used in research "are provided humane care and treatment," the statute requires the USDA to promulgate "standards to govern the humane handling, care, treatment, and transportation of animals." 7 U.S.C. § 2143. Those general standards include "minimum requirements" for "handling, housing, feeding, watering, sanitation, ventilation . . . [and] adequate veterinary care." 7 U.S.C. § 2143(a)(2)(A). The statute also requires the USDA to promulgate species-specific provisions, including a standard requiring a "physical environment adequate to promote the psychological well-being of primates." 7 U.S.C. § 2143(a)(2)(B).

22. With respect to "animals in research facilities," the AWA includes additional requirements. 7 U.S.C. § 2143(a)(3). Standards covering animal experiments must "ensure that

animal pain and distress are minimized," 7 U.S.C. 2143(a)(3)(A), and for procedures likely to produce such pain and distress, the principal investigator must "consider[] alternatives." 7 U.S.C. § 2143(a)(3)(B).

23. To ensure that these standards are met, the AWA provides that "[t]he 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*." 7 U.S.C. § 2143(a)(7)(A) (emphases added).

24. The AWA further provides that "[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) (emphases added).

25. Congress has also mandated that the USDA affirmatively disclose to the public all information generated by such annual inspections in a searchable database. 7 U.S.C. § 2146(a). This disclosure mandate includes all inspection reports, "all reports documenting all Animal Welfare Act non-compliances observed by USDA officials," all "enforcement records," and "all reports or other materials documenting any non-compliances observed by USDA officials." 7 U.S.C. § 2146(a)(b).

B. USDA Proposal and Public Opposition to USDA Reliance on Third-Party Accreditation

26. Within the USDA, APHIS is tasked with meeting the requirements of the AWA, including the statute's mandates that the agency "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).

27. Prior to February 2019, the USDA interpreted this provision of the statute to require the agency to conduct a full inspection of each research facility at least once annually—i.e., an inspection of all aspects of the facility to ensure that it was operating in compliance with all applicable AWA standards.

28. In 2018, the agency solicited public comment on a potential new policy that would "recogniz[e] the use of third-party inspection and certification programs when determining APHIS inspection frequency at facilities licensed or registered under the Animal Welfare Act." 83 Fed. Reg. 2959 (January 22, 2018). As explained in the proposal, the agency was contemplating a "potential reduction in the frequency of APHIS inspections" for facilities that had received third-party certifications from organizations other than the USDA. *Id.*

29. In response to this proposal, many commenters specifically urged the USDA not to rely on AAALAC accreditation as a basis for reducing the frequency of inspections of research labs.

30. AAALAC is a private, non-profit industry-led organization founded in 1965 that runs a voluntary accreditation program for animal research programs.

31. AAALAC does not employ the USDA's AWA standards in determining whether to grant accreditation to a research facility. Instead, AAALAC states that its standards for accreditation are generally based on *The Guide for the Care and Use of Laboratory Animals* (Eighth edition) (National Research Council 2011), which employs a flexible performance and practice standard for assessing program outcomes, such as adequate sanitation, appropriate housing, or environmental enrichment. AAALAC site visitors use their judgment to determine if a research facility is meeting performance objectives, rather than ascertaining whether the

facility is operating in compliance with any specific AWA standard or any other engineering requirement.

32. While AAALAC does not disclose the exact number of facilities it accredits, at least 667 facilities in the United States pay annual fees to be accredited by it. Accredited facilities include major universities, hospital systems, pharmaceutical companies, and biotechnology companies.

33. Once accredited by AAALAC, a facility is reviewed once every three years to maintain its accreditation. Further, once accredited, a facility may qualify for one of four different categories, i.e. full, conditional, deferred, or probation—all of which count as AAALAC accreditation.

34. Under "conditional" accreditation, a facility has to correct any deficiencies by the time of the next annual report, or later according to the Accreditation Council's discretion.

35. Under "deferred" accreditation, an organization has two months to correct any deficiencies before being placed on probation.

36. Under "probationary" accreditation, a facility is given at least 12 months to correct a deficiency.

37. At no point during these various stages of accreditation does a facility lose its AAALAC accreditation. Therefore, a research facility that is under "conditional" accreditation, then "deferred" accreditation, and finally "probationary" accreditation, can continue to operate and remain "accredited" by AAALAC during that entire timeframe—upwards of 24 months.

38. AAALAC's "Council on Accreditation," the group that conducts site visits and program evaluations, comprises animal research practitioners drawn from the same scientific and

business community as the facilities seeking accreditation. Those facilities seeking accreditation fund AAALAC through initial application fees and subsequent annual fees.

39. In response to the USDA's proposed deference to third-party accreditors, commenters specifically advised the agency not to rely on AAALAC accreditation on the grounds that AAALAC lacks impartiality because it is funded by the same industry to which it grants accreditation, and its inspectors—called "site visitors" by AAALAC—are drawn from the same community.

40. Commenters also stressed that AAALAC accreditation by no means ensures compliance with the "minimum requirements" of the AWA. 7 U.S.C. § 2143(a)(2). For example, in response to the agency's request for public comment, People for the Ethical Treatment of Animals ("PETA") submitted a peer-reviewed study demonstrating that AAALAC-accredited laboratories were cited for AWA violations *at a rate higher than non-accredited facilities.*

41. PETA also provided the agency with detailed examples of AAALAC-accredited facilities that had been cited by the USDA for multiple, serious AWA violations, such as failure to provide anesthesia to animals as required, failure to provide for the psychological well-being of non-human primates, and multiple examples of animals who died by starvation or dehydration.

42. The Humane Society of the United States also provided the USDA with specific examples of AAALAC-accredited institutions that violated the AWA numerous times without ever losing their AAALAC accreditation. For example, a research facility in Texas was cited multiple times by the USDA in 2011 and 2013 for serious AWA violations, yet this facility never lost its AAALAC accreditation.

43. Commenters knew about these blatant violations at AAALAC-accredited facilities because at the time these inspections were conducted, USDA inspectors were still conducting full annual inspections, as required by the AWA, and these full inspection reports were made available to the public in the USDA's Reading Room pursuant to the affirmative disclosure requirements of FOIA. 5 U.S.C. § 552(a)(2).

44. Commenters also raised concerns that AAALAC site visits are infrequent and scheduled in advance so facilities can "clean up their act before the site visit team arrives."

45. Other commenters complained that, should the USDA implement such a third-party accreditation policy, oversight of laboratories would suffer because information produced by third-party programs, including AAALAC, are not available to the public. AAALAC describes its site visits as confidential peer-review "visits," rather than formalized inspections, and the entire process is kept completely confidential. Thus, all evaluations, including evidence of deficiencies and incident reports, are kept confidential between AAALAC and the facility under review. AAALAC does not report deficiencies to any government agency, including APHIS, and it also assures the facilities that this process, including all documents and reports, is not subject to FOIA.

46. On May 25, 2018, the USDA announced that after having "carefully considered" feedback from key stakeholders and the public, it had decided *not* to recognize third-party inspections or certifications "when determining the Agency's own inspection frequency under the Animal Welfare Act," noting that the agency found the "vast majority" of the comments received "to not be in favor of establishing new criteria for recognizing third party inspection and certification programs."

C. Plaintiffs Discover that the USDA Has Secretly Implemented its New Inspection Policy.

47. On July 9, 2020, Rise (formerly New England Antivivisection Society) and ALDF filed suit in this Court challenging the USDA's denial of their rulemaking petition to improve the AWA standard required to "promote the psychological well-being of primates" used in research. *New England Anti-Vivisection Society et al. v. Elizabeth Goldentyer*, No. 8:20-cv-02004-GJH (D. Md.). One of the reasons cited by the USDA for denying that petition was its assertion that:

> APHIS inspectors evaluate a facilities' compliance with the regulation during the inspection. *They examine and document all areas of care and treatment that are covered under the AWA, including the plan. The inspector also observes the regulated animals; inspects the facilities, including enclosure or housing materials space, and records*. If 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.*

USDA Petition Denial (October 10, 2019) (emphasis added).

48. However, at the time Plaintiffs received the agency's denial of their petition, they had unconfirmed information that, with regard to AAALAC-accredited facilities, USDA inspectors were *not* conducting full inspections annually. If true, this would mean that, contrary to the USDA's assertion, the inspectors were *not* "examin[ing] and document[ing] all areas of care and treatment that are covered under the AWA, including the plan," and therefore, they were also not annually "observ[ing] the regulated animals" or "inspect[ing] the facilities, including enclosure or housing materials space, and records." This also would necessarily mean that inspectors were not ascertaining whether the research facilities were "in full compliance with the AWA requirements" and hence were also not "document[ing]" any such "findings."

49. Because Plaintiffs were unable to confirm that the USDA was no longer conducting full inspections of AAALAC-accredited labs each year, they stated in their

Complaint that, "on information and belief," APHIS "recently informed its inspector of facilities accredited by the Association for Assessment and Accreditation of Laboratory Care ("AALAC") that they may *choose* which aspects of a particular facility they wish to inspect" and that "[t]his means that the inspectors are not even required to inspect *all* of the animals, *all* aspects of the facility, or even the environmental enrichment plans currently being used by such facilities when completing the annual inspections that are required by the AWA. 7 U.S.C. § 2143(a)(2)(B)." Complaint, No. 8:20-cv-02004-GJH, ¶ 70.

50. To document that such a policy did in fact exist, Plaintiffs submitted a FOIA request to the USDA to obtain access to any records that would reflect the existence of the policy.

51. When the agency failed to respond to Plaintiffs' FOIA request in a timely manner, Plaintiffs filed a FOIA suit in this Court to obtain access to those records. *New England Anti-Vivisection Society et al. v. Animal and Plant Health Inspection Service* and *United States Department of Agriculture*, No. 8:20-cv-03013-TDC (D. Md. filed October 16, 2020).

52. As a result of their FOIA case, Plaintiffs obtained hundreds of responsive records that showed that, despite the public's overwhelming objection to the agency treating third-party certifications as a positive factor in its evaluation of research facilities, and the agency's own pronouncement that it had decided *not* to implement any such policy, the USDA had nevertheless implemented a new Inspection Policy under which the agency no longer conducted full inspections of all facets of research labs that are accredited by AAALAC.

53. The documents released under FOIA show that in February 2019, APHIS "issued guidance that made it mandatory" for its inspectors to perform a "focused inspection at AAALAC-accredited research facilities." Under this guidance, APHIS inspectors may *only*

inspect one of three facets of each facility—*either* (1) the "animals" being maintained at the lab, (2) the "facilities," or (3) the "paperwork" each facility is required to maintain. In addition, under the new Policy, the inspector may also simply inspect a "sampling" of some or all of the above categories.

54. Under the new Policy, the USDA instructed its inspectors that when conducting their annual inspections of research facilities accredited by AAALAC, they are *prohibited* from conducting full inspections of each such facility, unless specifically requested to do so by the facility itself. APHIS inspectors may not even look at a single animal being used in research—including, for instance, thousands of primates who are subjected to grueling and painful research procedures—if the inspector chooses to review a mere "sampling" of the facility's paperwork.

55. Pursuant to the new Partial Inspection Policy, inspectors are required to "rotate [their] focus for each visit." This means that in the first year, the inspector may inspect only the animals; for the second year, the inspector may inspect only the facilities; for the third year, the inspector may inspect only the paperwork; and for the fourth year, the inspector may inspect a "sampling" of only *some* of one of these aspects of the facility.

56. Therefore, under this Partial Inspection Policy, *as many as four years may lapse before APHIS inspects a single animal that is the subject of the facility's research*.

57. Pursuant to this Policy, inspectors are also not allowed to ask the facility for proof that it is AAALAC-accredited or inquire as to the facility's current accreditation status. This means APHIS inspectors are prohibited from asking whether a facility has conditional, deferred, or probationary accreditation, any of which suggests known animal welfare deficiencies under AAALAC's own accreditation scheme.

58. However, as explained *supra*, ¶¶ 32-36, research facilities can receive AAALAC accreditation through a "site visit" every three years and maintain good standing *even while on probation for serious deficiencies*.

59. According to APHIS, this "focused" inspection of an AAALAC-accredited facility "counts as the facility's annual inspection," as required by the Animal Welfare Act, 7 U.S.C. § 2146(a).

60. Pursuant to the agency's new Partial Inspection Policy, APHIS has instructed its inspectors not to document on the inspection report "the area or areas the inspection was focused on." This means that the inspection reports generated pursuant to this Policy do not contain this information, and the public will not know from the inspection report, (a) what the inspector inspected; or (b) whether the research facility is in compliance with all of the standards of care required by the AWA and its implementing regulations.

61. The documents obtained under FOIA further reveal that APHIS instructed its inspectors not to disclose the existence or the contours of the Partial Inspection Policy outside of the agency, stating that there would "be no stakeholder announcement" of the new Policy. Instead, APHIS instructed its inspectors to convey the Partial Inspection Policy only to the specific facilities that they inspect.

62. The documents obtained by Plaintiffs also demonstrate that APHIS has informed its inspectors that the Partial Inspection Policy and the way in which it is implemented would not be included in the agency's publicly available Inspection Guide. In fact, the most recent version of the agency's official Inspection Guide, issued in November of 2021, does not contain any mention of the new Partial Inspection Policy.

63. The USDA did not inform the public that it had instituted a new Partial Inspection Policy that applies to AAALAC-accredited research labs.

64. Because the USDA did not inform the public that it had implemented a new Partial Inspection Policy for research labs, it did not explain to the public the basis for its change in practice from doing full annual inspections of research labs to now only doing partial annual inspections of AAALAC-accredited research labs.

E. Additional Facts Giving Rise to Plaintiffs' Claim

65. Prior to February 2017, USDA inspection reports were made available to the public in the USDA's Reading Room pursuant to the affirmative disclosure requirements of FOIA. 5 U.S.C. § 552(a)(2). However, in February 2017, the USDA, under the Trump Administration, removed that information from the agency's public Reading Room.

66. On December 20, 2019, Congress amended the AWA to provide that APHIS "shall . . . make publicly available via searchable database, in their entirety without redactions except signatures . . . *all final Animal Welfare Act inspection reports*, *including all reports documenting all Animal Welfare Act non-compliances observed by USDA officials*." 7 U.S.C. § 2146(a) (emphasis added).

67. Due to the agency's Partial Inspection Policy, inspectors are not conducting full inspections each year of AAALAC-accredited facilities. This makes it impossible for the USDA to fulfill its statutory duty to "conduct follow-up inspections *as may be necessary until all deficiencies or deviations from [AWA] standards*" are cured. 7 U.S.C. § 2146(a). Without a full inspection covering every aspect of a research facility including animals, premises, buildings, and records, the USDA cannot ascertain what "deficiencies" and "deviations" need to be corrected as required by the statute.

PLAINTIFFS' CLAIM FOR RELIEF

68. Plaintiffs re-allege and incorporate by reference paragraphs 1 through 66as though fully alleged herein.

69. Defendants' Partial Inspection Policy violates the AWA which expressly provides that the USDA "shall" inspect each research facility annually for the purpose of ascertaining whether it is complying with all applicable AWA standards. 7 U.S.C. § 2146(a). Accordingly, the Inspection Policy is "not in accordance with law" within the meaning of the APA, 5 U.S.C. §706(2)(A).

70. Defendants' decision to implement the new Partial Inspection Policy was also arbitrary and capricious and an abuse of discretion within the meaning of the APA, 5 U.S.C. § 706(2), in light of all of the limitations that attend AAALAC accreditation and the fact that that AAALAC-accredited facilities have a *higher* rate of AWA violations than non-AAALAC-accredited facilities—all of which was explained and documented for the agency in comments on the agency's proposal to recognize third-party inspections or certifications.

71. APHIS also improperly revised its inspection policy without providing a reasoned explanation for this change in policy, and despite overwhelming evidence that deferring to AAALAC accreditation harms animals used in research, undermines the AWA, and deprives the public of information mandated by statute. For all of these reasons, the agency's decision to implement this new policy is arbitrary and capricious within the meaning of the APA, 5 U.S.C. § 706(2).

72. By deferring to AAALAC accreditation to fulfill its statutory obligation to inspect each research facility annually to ensure that it is in compliance with all applicable AWA standards, the USDA has unlawfully delegated its statutory obligation to a non-governmental

entity in violation of the AWA, 7 U.S.C. § 2146(a). This unlawful delegation of authority is also arbitrary and capricious, and an abuse of discretion within the meaning of the APA, 5 U.S.C. § 706(2).

73. The agency's violations of law injure Plaintiffs in the manner described in paragraphs 5 to 16 herein.

WHEREFORE, Plaintiffs respectfully request that this Court:

1. Declare that Defendants' Inspection Policy is unlawful;

2. Set aside the unlawful Inspection Policy;

3. Award Plaintiffs their costs and attorneys' fees; and

4. Award Plaintiffs such other and further relief as the Court may deem just and proper.

Respectfully submitted,

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