



May 26, 2015

Regulatory Analysis and Development
Program Planning and Development
Animal and Plant Health Inspection Service (APHIS)
U.S. Department of Agriculture (USDA)
Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Docket No. APHIS-2014-0050
Petition to Define Alternatives to Procedures that May Cause Pain or Distress and to Establish Standards Regarding Consideration of these Alternatives

Submitted online at <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0050>.

The American Psychological Association (APA) appreciates the opportunity to comment on the petition to define alternatives to procedures that may cause pain or distress and to establish standards regarding consideration of these alternatives (Docket No. APHIS-2014-0050). The APA Committee on Animal Research and Ethics (CARE) has reviewed the petition and assessed the impact of the proposed amendments to the animal welfare regulations (AWRs) on psychological research with nonhuman animals. CARE is a governance committee of the APA, representing a membership of more than 122,500 researchers, educators, clinicians, consultants, and students. CARE takes the lead in developing and regularly updating APA's guidelines for the humane care and treatment of nonhuman animals in research. APA considers humanely conducted research with nonhuman animals to be an integral component of the science of behavior.

APA appreciates the United States Department of Agriculture Animal and Plant Health Inspection Service's (APHIS) continued efforts to ensure the humane care and treatment of nonhuman animals in research, but has serious concerns about amending the AWRs as proposed by the petitioners. APA strongly recommends that the USDA **not** initiate rulemaking, as requested by the petitioners. AWRs cover a broad range of activities using animals including "elements of research, testing, or teaching procedures" (9 CFR Part 1; Section 1.1). Accordingly, the language in the current regulations allows for flexibility in interpretation depending on the goals and implications of the specific activity under consideration. APA believes that it is misguided to amend regulations based on, by the petitioners' own account, a small number of instances that have to do solely with the use of animals in *training*, while failing to provide a single example related to research that warrants amendments to the regulations. Furthermore, APA believes that the proposed amendments would only result in additional regulatory

burden, with little, if any, improvement in the welfare of the laboratory animals. More importantly, the proposed changes would seriously impede valuable research that can contribute to enhancing the well-being of both people and other animals.

Adding a definition of the term *alternatives*

APA strongly recommends that the AWRs not be amended to include a definition of the term *alternative*, primarily because codifying the term will render it unresponsive to rapidly changing developments in science and technology which undergird refinement of research procedures as well as replacement of animal subjects in research. In addition, the AWRs incorporate performance standards which are outcome-based and provide Institutional Animal Care and Use Committees (IACUCs) the flexibility to make determinations on a protocol-by-protocol basis. These performance standards are critical for allowing scientists to be responsive to new information that has implications for research procedures and laboratory animal care. Scientists are on the forefront of quickly evolving fields and have the proper expertise to ensure that new knowledge is appropriately incorporated into performance standards; taking away this flexibility by codifying the term would hinder progress both in science and laboratory animal care.

Clarify the existing definition of a *painful procedure*

APA has serious concerns about amending the existing definition of *painful procedure* in order to codify a long-standing APHIS policy (54 Fed. Reg. 1989) that a procedure should be considered to be *painful* if it may cause more than momentary or slight pain or distress to the animals, even if this pain is subsequently relieved through anesthesia. APA believes that the policy as written is misguided, only serves to increase regulatory burden, without improving the welfare of research animals. Instead, APA recommends that assessing pain in research with nonhuman animals should parallel the evaluation of risks of harm in research with human participants. Levels of pain should be assessed in terms of the experiences of the species in everyday life events and routine procedures. Therefore, a study requiring a procedure with an anesthetized animal that does not feel pain during the procedure and feels only minimal pain while recovering would be considered a procedure that causes low or no pain, given that a complete absence of any pain or discomfort is not a reasonable expectation of any animal's daily life experience.

APA is also concerned that the use of the term *pain* in the USDA regulations pivots around the definition of pain from a purely human perspective. This is a subjective definition that disregards the well-being and needs of specific species. An important limitation of applying human subjective judgments of pain to research procedures is that such criteria ignore or circumvent the unique sensory, perceptual, and expressive systems of different species. Pain cannot be measured on an absolute scale, nor can it be scaled and compared across species. Instead, the experience of pain can be placed on a continuum from minimum threshold levels of perception to maximum levels of tolerance. Pain may not be maladaptive or produce distress until it exceeds a level of tolerance where it dominates behavior. An animal can be distressed without pain and may experience some pain without distress. It is broadly recognized that animals can experience pain, as evidenced by efforts to avoid or escape noxious stimuli. It is important that the IACUC have the flexibility to evaluate these nuanced issues in a rigorous manner on a protocol-

by-protocol basis. Amending the definition of painful procedures as proposed by the petitioners would obviate the flexibility that is afforded by the current regulations.

Establishing standards governing the consideration of alternatives

APA challenges the petitioner's assertion that "because of ambiguities in the regulations, research facilities have sometimes construed them to mean that cursory deliberation regarding alternatives suffices to meet the regulatory and statutory requirement to consider alternatives." Compliance with the detailed requirements enshrined in the AWRs [9 CFR Part 2, Sections 2.31(d)(1)(ii) and (e)] can by no means be deemed "cursory deliberation." Furthermore, the assertion implies the unwarranted claim that scientists are uninterested in the welfare of research animals. And last but not least, the assertion perpetuates the myth promulgated by entities opposed to animal research that scientists use animal models because it is easier and cheaper than conducting research with human participants.

At the local level, compliance with regulatory requirements is overseen and enforced by IACUCs. Per regulatory mandate, scientists are required to provide the IACUC with detailed justifications for the use of animals in research and for the use of procedures that might cause more than momentary or slight pain, as well as to describe methods that will be implemented for reducing or eliminating pain. In addition to external oversight by the IACUC, scientists honor their moral obligation to weigh potential benefits and harms when designing a study and to attend to the welfare of animal subjects, for both ethical reasons and also to ensure scientifically valid results. Lastly, the 3 R's (reduction, refinement, and replacement) are well established in the scientific process. Based on the scientific literature, researchers carefully consider the species, numbers of animals, and procedures in the initial stages of designing studies. Thus, APA believes that the current regulations, and the interpretation of the regulations at the local level (by IACUCs) is effective in addressing the broad range of research conducted with nonhuman animals. In addition, the flexibility for local determination provided by the current regulations is in the best interest of the animals' welfare.

Responses to the Questions Posed by the Notice of Petition:

1. Should APHIS establish regulatory standards for consideration of alternatives to procedures that may cause more than momentary or slight pain or distress to animals?

No, for the reasons stated above. Amendments to regulations would increase administrative burden, with no clear enhancement of animal welfare. Establishing regulatory standards that go beyond the criteria listed in 9 CFR Part 2, Sections 2.31(d)(1)(ii) and (e) would not take into account the nuances of a wide range of research with nonhuman animals, and thus, significantly impede valuable research that could benefit both humans and other animals.

2. What constitutes an alternative to a procedure that may cause more than momentary or slight pain or distress? If we amend the AWA regulations to define the term alternative, what definition should we use?

APA does not believe that the regulations need to be amended to include a definition of the term alternative. The definition provided in the USDA Animal Care Resource Guide under Policy 12 has been in place for nearly 15 years, and is well understood by both researchers and IACUCs. Allowing the research community to avail of the flexibility inherent in a policy, as opposed to the mandatory nature of regulatory language, is in the best of interest of the animals as well as society in general, as beneficiaries of scientific discoveries and findings.

3. What constitutes a thorough consideration of alternatives? Does this differ depending on the nature of the research conducted? If so, how?

The question posed by the USDA in response to the petition reflects a lack of appreciation for the research enterprise/scientific process. One of the first steps, if not THE first step in designing a study is undertaking a comprehensive search of the literature, which will conclusively identify alternatives, if any. In addition, as experts in the particular field, researchers (and potentially IACUC members) would be well aware of whether or not alternatives to the use of animals and/or alternative procedures exist. To ensure that researchers have indeed given alternatives serious consideration, IACUCs require that scientists justify why the use of animals is necessary and why alternatives would not be appropriate.

4. Who should make a determination regarding the thoroughness of a primary investigator's consideration of alternatives: The IACUC for a facility, APHIS, or both parties?

The determination should be made by a member of the IACUC with the appropriate expertise. When necessary, the IACUC should seek consultation from an expert. We believe that involving APHIS in the process would only unnecessarily delay the review process and impede research.

5. If the IACUC and APHIS should jointly make a determination, which responsibilities should fall to APHIS and which to the IACUC in terms of evaluating thoroughness?

The IACUC and APHIS should not make a joint determination.

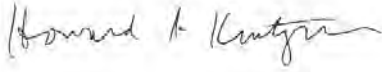
6. What documentation should the primary investigator provide to demonstrate that he or she has done a thorough consideration of alternatives?

The documentation requirements specified in the USDA Animal Care Resource Guide under Policy 12 are more than adequate for demonstrating that the researcher has done a thorough consideration of alternatives. In addition to, or in lieu of a literature search with appropriate references, a reasoned statement of what alternative(s) might exist and why they will not work in a particular study provides the IACUC with the necessary information to determine the researcher's effort to consider alternatives.

In conclusion, APA strongly reiterates its recommendation that the USDA not initiate rulemaking as proposed by the petitioners. APA wholly supports the need for humane care and treatment of nonhuman animals in research. However, we are also concerned that the proposed amendments would impose a significant regulatory and administrative burden on the research enterprise and would restrict new forms of research, thus hindering the advancement of knowledge and the improvement of both human and animal welfare. Thus, APA strongly recommends that USDA **not** make the proposed

amendments to the AWRs. If you have any questions, or if APA can provide any further information, please feel free to contact me at 202-336-6000 or by email at researchethics@apa.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard S. Kurtzman". The signature is fluid and cursive, with a long horizontal stroke at the end.

Howard S. Kurtzman, PhD
Acting Executive Director for Science