MARINE MAMMAL COMMISSION

21 October 2020

Mr. Mark Davidson, Acting Administrator
Animal and Plant Health Inspection Service
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Docket No. APHIS-2019-0001

Dear Mr. Davidson:

The Marine Mammal Commission (the Commission), in consultation with its Committee of Scientific Advisors on Marine Mammals, has reviewed the Animal and Plant Health Inspection Service's (APHIS) 17 September 2020 notice (85 Fed. Reg. 57998) regarding its proposed revisions to the implementing regulations for the Animal Welfare Act (AWA; 9 C.F.R. § 2.30 et seq.).

Background

APHIS proposed to remove from its implementing regulations the requirements that (1) a research facility update its registration information every three years, (2) a research facility request an inactive status if it no longer uses, handles, or transports animals under the AWA, (3) the Chief Executive Officer (CEO) or Institutional Official (IO) sign and certify the annual report of each facility, and (4) Institutional Animal Care and Use Committees (IACUCs) conduct annual reviews of research activities, replacing these with reviews at least every three years. APHIS indicated that the proposed revisions to the AWA implementing regulations would address the reforms called for in Executive Order 13777, "Enforcing the Regulatory Reform Agenda,"[1] and thus are intended to remove unnecessary directives and/or reduce the regulatory burden on research facilities.

Research facility requirements

Under section 2.30(a)(1) of the AWA implementing regulations, a research facility currently is required to complete and submit a registration form every three years, which includes the registrant's contact information, U.S. Department of Agriculture (USDA) registration certificate number(s), and types of animals held at the facility. APHIS determined that the requirement is duplicative, since registrants are already required to notify APHIS of a change to any of the same information within 10 days of the change's occurring (85 Fed. Reg. 57999). Most of that information also is provided by facilities in their required annual reports. As such, the proposed revision to section 2.30(a)(1) of the implementing regulations would eliminate the requirement to update a facility's registration every three years. The Commission agrees that the current regulations are

[1] See 82 Fed. Reg. 12285.

unnecessarily duplicative and recommends that APHIS remove the requirement that a research facility complete and submit a registration form every three years.

In addition, a research facility that no longer uses, handles, or transports animals currently is required to request an inactive status and submit annual reports. A facility must notify APHIS and request that its registration be canceled to become unregistered officially. Under the proposed revisions, facilities that become inactive would automatically become unregistered after two years without animals[2] and would need to re-register at least 10 days prior to resuming operations[3] (85 Fed. Reg. 57999). APHIS believes that removing the notification requirement would reduce the administrative burden on facilities (85 Fed. Reg. 57999). Given that a facility would have a two-year period before it became unregistered, allowing for a temporary break in maintaining or transporting animals, the Commission concurs with the reasoning behind these proposed revisions and recommends that APHIS automatically unregister a facility after two years of not holding, using, or transporting animals.

Third, under section 2.36(a) of the AWA implementing regulations, the CEO or IO of a research facility that holds, uses, or transports animals currently is required to sign and certify the annual report to APHIS. Under the proposed revisions to the implementing regulations, APHIS would no longer require the signature of the CEO or IO on the paper version of the annual report (85 Fed. Reg. 58000). Instead, the facility representative could submit the annual report electronically on behalf of the CEO or IO, while maintaining the assurance requirements regarding the content of the annual report and practices at the facility. APHIS indicated that the proposed revision would prevent identity theft through written signatures (85 Fed. Reg. 58000), although the extent or seriousness of this issue in the past is not clear. Regardless, since the CEO or IO is ultimately responsible for making any necessary modifications to a facility and for ensuring that research protocols are modified as necessary for animal welfare purposes, his or her signature on an annual report confirms that he or she is aware that such modifications are needed. If the annual report was instead submitted by the facility representative electronically, the CEO or IO may not be aware that modifications are needed for the facility or its research protocols to be in compliance with the AWA. Thus, this might reduce the accountability on the part of the CEO or IO to ensure that the necessary modifications are made. Therefore, the Commission recommends that APHIS revise its implementing regulations to allow digital signatures and submittals of annual reports but continue to require that the CEO or IO sign and certify the annual report for any facility that holds, uses, or transports animals.

IACUC requirements

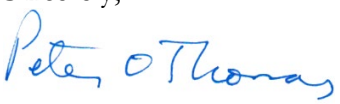
A research facility's IACUC is currently required to review activities involving care and use of research animals on an annual basis (see section 2.31(d)(5) of the AWA implementing regulations). During those reviews, an IACUC determines whether activities have been conducted in accordance with approved research protocols. The proposed revisions to the AWA implementing regulations would require that an IACUC review research activities at least every three years instead of annually[4] (85 Fed. Reg. 58000). The Commission finds APHIS's proposed change concerning.

[2] As indicated by two consecutive years of annual reports that show a facility did not hold, use, or transport animals.
[3] A facility also could voluntarily request cancellation of its registration.
[4] A facility could still direct its IACUC to conduct an annual review of its activities involving care and use of research animals, but it would no longer be a requirement under the revised AWA implementing regulations.

Under the revised implementing regulations, any violation of IACUC-approved protocols, such as performing procedures on animals in addition to what were initially approved or experiencing more animal mortalities than were initially approved, would not necessarily be brought to the attention of the IACUC until the three-year review, by which time it could be too late, maybe even far too late, to take appropriate action. As another example, a drug or procedure initially approved could be found by the broader scientific community to be no longer safe for an animal, but an IACUC might only reconsider its use by researchers during the three-year review. By delaying the IACUC's review, such an issue may not be recognized and mitigated for up to three years. Thus, the revised review requirements could compromise the health and wellbeing of animals for an extended period of time. Therefore, the Commission recommends that APHIS continue to require a facility's IACUC to perform a complete review of the activities involving care and use of research animals on an annual basis and refrain from increasing the review interval to every three years.

The Commission appreciates the opportunity to review APHIS's proposed revisions to its implementing regulations for the AWA. Please contact me if you have any questions regarding the Commission's recommendations.

Sincerely,



Peter O. Thomas, Ph.D.,
Executive Director

cc: Dr. Barbara Kohn, Animal and Plant Health Inspection Service