



FASEB

Federation of American Societies
for Experimental Biology

Representing Over 130,000 Researchers

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Mike Tuck
Management Analyst
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4700 River Road, Unit 84
Riverdale, Maryland 20737
James.M.Tuck@aphis.usda.gov

Dear Mr. Tuck,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the request for input pertaining to the recognition of third-party inspection and certification programs as positive factors in determining Animal and Plant Health Inspection Service (APHIS) inspection frequencies at facilities licensed or registered under the Animal Welfare Act (AWA). FASEB is a coalition of 30 life science societies representing more than 130,000 biological and biomedical researchers, many of whom are involved in the humane care and use of animals in research and education. We encourage APHIS to utilize third-party inspections, such as AAALAC International accreditation, as factors in the already established Risk Based Inspection System¹, which allows for “more frequent and in-depth inspections at facilities with a higher risk of animal welfare concerns, and fewer at those that are consistently in compliance.”

FASEB recognizes that Section 2146 of the AWA requires APHIS to inspect registered research facilities at least annually. While the frequency of inspections can only be altered by amendment of the AWA, intensity of inspections could be altered based upon program accreditation and compliance history. The comments below highlight reasons why FASEB supports the consideration of third-party inspections or certifications as positive factors towards inspection intensity.

The regulated community has demonstrated a commitment to animal welfare and compliance with the AWA and its Regulations.

AAALAC International is a voluntary accrediting organization that promotes the humane treatment of animals in science. At the Symposium on Animal Welfare and Scientific Research: 1985 to 2010, Christian Newcomer – then AAALAC International Executive Director – provided an overview of the evolution of animal welfare through AAALAC’s perspective. In his presentation, he described how mandatory findings (MFs) and Suggestions for Improvement (SFIs) had decreased after the 1985 Amendments to the AWA and Health Research Extension Act, which provided the statutory mandate for the Public Health Service Policy on Humane Care and Use of Laboratory Animals. He noted that MFs

¹ https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/ct_awa_risk_based_inspection_system

related to facilities at AAALAC International site visits had decreased from an incidence of 0.42 in 1986 to 0.03 in 2008². SFIs related to animal facilities also fell in that same time period (1986, incidence = 1.29; 2008, incidence = 0.15). Approximately 700 of the most productive, high quality research institutions in the United States have AAALAC International accreditation.

Additionally, a National Association for Biomedical Research (NABR) analysis indicates that the regulated community continues to reduce the number of noncompliant items (NCIs) discovered during APHIS inspections (2015 = 561, 2016 = 470, 2017 = 380). Eighty-two percent of the inspections that APHIS conducted in fiscal year (FY) 2017 were free from noncompliance. Of the 380 total NCIs found during FY 2017 APHIS inspections, 84 percent (329) were noncritical, meaning they did not pose a direct risk to animal welfare.

A minority of research facilities account for a larger number of AWA citations

The same NABR analysis noted that only 24 percent of active research facilities (227 of 959) were cited for noncompliance. Of those, approximately 60 percent had only one NCI. This suggests that a risk-based approach to inspection, including utilization of third-party inspections/certifications as one factor, would improve efficiency and compliance with the AWA and its Regulations.

While APHIS cannot alter the frequency of inspection at this time, FASEB encourages the use of third party inspections or certifications as factors in their risk-based inspection system. These third parties would supplement, not supplant, the APHIS inspection process thereby allowing APHIS to use its limited resources focusing on programs that may present a higher risk.

FASEB thanks you for the opportunity to comment on this proposal. Please feel free to contact us should you have any questions or require any clarifications.

Sincerely,



Thomas O. Baldwin, PhD
FASEB President

² ILAR J. 2011, Volume 52, Supplement