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United States Department of Agriculture Animal and Plant Health Inspection Service Station 3A-03.10 4700 River Road, Unit 118 Riverdale, MD 20737

RE: Advance Notice of Proposed Rulemaking on Wild and Exotic Animal Handling, Training of Personnel Involved with Public Handling of Wild and Exotic Animals, and Environmental Enrichment for Species [Docket No. APHIS 2022-0022]

Submitted electronically via regulations.gov and via e-mail: <u>lance.h.bassage@usda.gov</u> and betty.j.goldentyer@usda.gov

Dear Drs. Bassage and Goldentyer,

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to provide comments on the Advance Notice of Proposed Rulemaking (ANPR) seeking input on standards for handling captive wild and exotic animals, as well as strengthening environmental enrichment for regulated species. As a coalition of 27 member societies across a broad range of scientific disciplines, we commend the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) for ensuring regulations reflect the best available science. FASEB supports the research community's responsibility to uphold animal care and welfare and recognizes that standards continually evolve according to the latest data and professional standards to achieve optimal animal health and excellent science. As part of this effort, FASEB's comments focus on the questions related to environmental enrichment for regulated species, specifically those used in biomedical research. In reviewing stakeholder comments and planning next steps in the rulemaking process, we urge USDA APHIS to ensure that potential new requirements result in concrete benefits to animal welfare and do not pose an additional administrative or financial burden for regulated entities, particularly for small and under-resourced institutions.

What, if any, general environmental enrichments should be required for all species?

A healthy environment plays a critical role in enhancing animal welfare and fostering high-quality research that benefits humans and animals alike. Therefore, consideration for environmental conditions such as enrichment remains an essential component of the research process. While current laws and regulations require environmental enrichment only for nonhuman primates and marine mammals, environmental enrichment is widely practiced for numerous species across many institutions and research

facilities. To accommodate the diverse needs of various species, FASEB supports current institutional practice that use enrichments to engage multiple sensory systems, including visual (e.g., mirrors, videos, brightly colored mobiles), auditory (e.g., music, natural sounds, etc.), tactile (e.g., inanimate objects, etc.), taste (e.g., devices to promote foraging), olfactory (novel scents, etc.) and cognitive (e.g., touch screens, computers, etc.). In many cases, exercise and socialization are incorporated for larger species such as dogs and nonhuman primates that benefit from increased physical activity and contact with conspecifics and/or humans.

While FASEB concurs that the psychological, physical, and behavioral health of animals remains critically important for overall welfare and research productivity, establishing a "one-size-fits-all" environmental enrichment approach could jeopardize scientific progress and disproportionately affect small, under-resourced institutions. Smaller institutions, for example, are more likely to be limited in research space for housing animals. Institutions may be less inclined to allow researchers to utilize certain species based on environmental requirements, regardless of the scientific merit of their research and species model system. For environmental enrichment to be effective, a careful assessment of feasibility and sustainability is required, based on existing resources, infrastructure, and administrative bandwidth. Given that these characteristics vary across institutions and research facilities, it is critical for current and future regulations to be flexible enough that regulated entities can implement requirements according to their individual needs. Prior to issuing a new rule, FASEB encourages USDA APHIS to first engage with the stakeholder community about the enrichment practices already in widespread use. This includes integrating perspectives frequently overlooked yet vital for effective animal care and management such as farm animal welfare and compassion fatigue for all animal caretakers, veterinarians, and technicians. One possible mechanism to accomplish this includes a survey or listening sessions with specific questions related to animal welfare, veterinary oversight, animal monitoring, farm animal science, and useful strategies for balancing administrative workload as well as staff psychological health. This information can facilitate the agency's efforts to determine which areas warrant further action in a sustainable manner that does not unnecessarily place smaller institutions at a disadvantage.

Additionally, given the highly diverse care and husbandry needs of various species used in biomedical research, FASEB is concerned that requiring broad environmental enrichment requirements will inadvertently endanger animal health and safety. While novel devices and structures facilitate a more engaging environment, unanticipated events are more likely to occur when environments are made increasingly complex. This includes potential animal injury, either to themselves or another animal. As noted earlier, active stakeholder engagement should remain a key part of USDA APHIS' decision-making process, similar to the agency's approach to <u>developing standards</u> for birds not used in research. Furthermore, the agency could consider coordinating with the National Institutes of Health (NIH) and AAALAC International to align future regulations with guidance widely adopted by the biomedical research community, such as the *Guide for the Care and Use of Animals*. FASEB encourages policy harmonization across federal agencies—as required by the 21st Century Cures Act—and considers such coordination a valuable opportunity to reduce potential confusion and burden for investigators while protecting animal health and care.

What environmental enrichments addressing psychological needs should be required for social species (in general or for particular species)?

Recognizing the complex needs of social species, FASEB recommends new guidance about psychological enrichment be limited to species whose social arrangement needs are well-documented and practiced. While species-, sex-, and age-appropriate psychological enrichment can significantly improve animal welfare by eliminating abnormal behaviors and reducing stress and aggression, poorly implemented plans could exacerbate negative behaviors and create an unsafe environment for both animals and humans. Therefore, we strongly recommend that future guidance be based on scientific evidence that accounts for species' psychological needs, including individual differences between animals of the same species or strains.

Scientists, veterinarians, and animal care experts at the National Primate Research Centers play a leading role in effectively developing and implementing environmental enrichment plans. To maximize primate environment in a manner that advances psychological well-being, these centers account for a species' natural history and their cognitive and behavioral needs, as well as outcome measures needed to assess enrichment efficacy. For example, minimizing abnormal or self-injurious behavior requires a baseline rate of such behavior and comparison following enrichment. As a second example, to assess whether enrichment reduces stress, many primate researchers and veterinarians evaluate the hypothalamic-pituitary-adrenal axis through cortisol measurements (Coleman and Novak, 2017).

However, many of these practices have yet to be standardized for other social species. FASEB recommends engaging with the research, veterinary, and farm community before publishing environmental requirements to ensure new regulations for additional species align with scientific evidence and proven methods that enhance animal welfare. Specific consideration is warranted for potential within-species differences to truly optimize social conditions and protect animal safety. Finally, to facilitate transparency and awareness, FASEB recommends the USDA share the scientific justification for potential regulations in a manner that is readily available to investigators, IACUCs, and administrators,

What environmental enrichments addressing enclosure space, lighting, and design to allow for species-typical behaviors should be required for animals in general, for certain taxa of animals, or for particular species?

FASEB requests USDA APHIS refrain from establishing universal space, lighting, and design requirements until concrete evidence of improved animal welfare has been demonstrated and widely accepted. While a significant number of studies have shown the benefits of providing animals with adequate housing and space to promote natural behaviors, a considerable amount of information remains unknown for several species. In cases where evidence is known, research facilities ensure that the necessary enrichments are provided. For example, enriched housing for pigs (e.g., straw bedding or peat) reduces damaging behavior while increasing their activity and play behavior (Luo et al., 2020). However, because there is less evidence about ideal environments for many other species used in research, agencies should dedicate resources to understanding this topic prior to establishing a "one-size-fits-all" policy that may induce unintended consequences for animal health. Furthermore, it is critical for the agency to consider the institutional feasibility of implementing potential new requirements and appreciate the challenges regulated entities currently face, including space limitations, budget constraints, and ongoing staff shortages. Potential strategies to consider in the agency's decision-making process include partnering with animal behaviorists, veterinarians, and farm managers to solicit feedback on best practices for enhancing enclosure space, and hosting listening sessions with the extramural community to assess the

impact new requirements would have on research productivity, administrative burden, staff morale, and animal husbandry.

Secondly, before new requirements are mandated, a strong understanding of the role of extrinsic factors on research outcomes is necessary. Conducting animal studies requires a delicate balance of supporting animal welfare while controlling for outside variables—including vital enrichments—to enable research rigor and reproducibility. A key concern for FASEB in publishing universal enrichment requirements is the introduction of heterogeneity between animals, thus further complicating the research process and impeding the research community's collective goal to enhance research reproducibility. This is particularly difficult considering species-specific differences. For example, circadian activity and ambient temperature requirements significantly vary between rodents and nonhuman primates. As a nascent field with more questions than answers, we encourage USDA APHIS to support studies that evaluate the relationship between extrinsic factors (ambient temperature, lighting levels, vibration, cage density) and animal enrichment and their joint impact on experimental results. As highlighted by the NIH Advisory Committee to the Director Working Group on Enhancing Rigor, Transparency, and Translatability in Animal Research in their final report, a systematic characterization of the effects of extrinsic conditions on various biological factors has yet to be done (Recommendation 4.3, pgs. 19-20). Before issuing a new rule and to facilitate data-driven policymaking, FASEB recommends USDA APHIS partner with NIH to examine how extrinsic factors can be effectively integrated into environmental enrichment programs without negatively affecting animal physiology, behavior, and overall research results.

If we choose to require a written plan, what specific requirements should the attending veterinarian consider when reviewing and/or approving the written plan?

The Federation recognizes the Animal Welfare Act's requirement for research institutions to establish written environmental enrichment plans for nonhuman primates but does not concur with extending this standard to all species. Writing and approving a written plan creates an institutional burden in terms of paperwork load, veterinarian time to review and approve plans, as well as continued staff management and monitoring to ensure proper plan implementation. Furthermore, given the need for animals to experience a variety of stimuli, it is impractical for animal care staff to predict the care and needs of research animals far in advance; alternative options and spontaneous changes frequently occur to accommodate animals' health, safety, and variable behavior.

Moving forward, FASEB strongly recommends USDA APHIS adopt a measured approach in developing next steps and potential rule changes. This approach should largely depend on the feedback and expertise of institutional attending veterinarians that closely work with animals and whose responsibility would be to review and approve written plans. These individuals understand animals' enrichment needs as well as current institutional practices to provide for these needs. Additionally, we advise the agency to specifically examine how potential new requirements—such as a written plan—may be enforced and their subsequent impact on institutional reputation. The scientific community remains dedicated to upholding animal welfare and frequently demonstrate this commitment by exceeding current standards and law. However, potential noncompliances are commonly exploited by animal rights groups to intimidate scientists and deter federal support for lifesaving animal studies. Enabling these opportunities, such as possible citations for violating written plans, further endangers the biomedical research enterprise and could create an untenable environment for future scientists and veterinarians.

What direct costs may be associated with providing environmental enrichment for the potentially affected animals in each category?

FASEB appreciates USDA APHIS' consideration for the direct costs associated with providing environmental enrichment, as budget constraints pose challenges for institutions to implement evolving federal requirements. By establishing universal environmental enrichment requirements, we are concerned that institutional financial strains will deepen and disproportionately impact institutions with fewer resources. Such outcomes may jeopardize animal health and well-being, a result counterintuitive to the goals of the Animal Welfare Act and the agency's overall mission.

Scientists, veterinarians, and animal care staff recognize that good science and good animal care are inextricably linked. Therefore, a significant portion of time, money, and staff are already dedicated to an institution's animal care program. Adding additional requirements, such as environmental enrichment, will increase costs for numerous components of these programs, including but not limited to: purchasing, processing, sanitizing, per diem rates, infrastructure expansion, and most importantly additional veterinary and administrative staff. As institutions continue to experience the effects of the post-pandemic era—labor shortages, supply chain deficiencies, and funding deficits—FASEB urges the agency to reconsider amending regulations that will exacerbate these circumstances. In addition to the increased costs, adding redundant requirements that may not be suitable to each institution's needs will complicate animal care programs and potentially discourage valuable veterinary and animal care staff from continuing work in the field. While direct costs to provide environmental enrichment will be substantial, FASEB encourages USDA APHIS to also consider the indirect costs that may result from broad regulatory changes.

FASEB appreciates the opportunity to provide comments on environmental enrichment standards for regulated species. As a multifaceted component of the research process, it is essential for USDA APHIS to engage with the appropriate experts to ensure potential new enrichment requirements are evidence-based, institutionally feasible, and of concrete benefit to animal welfare. Additional consideration is necessary for potential animal injury and within-species differences. Given the breadth and complexity of this issue, we recommend USDA provide ample time (e.g., at minimum 90 days) for the stakeholders to submit thoughtful responses to the forthcoming Notice of Proposed Rulemaking. We appreciate the agency's commitment to this topic and look forward to future engagement opportunities to collectively advance animal health and welfare.

Sincerely,

Kevin C. Kregel, PhD FASEB President