



June 25, 2008

Docket No. APHIS-2006-0024
APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Minimum Age Requirements for the Transport of Animals

To Whom It May Concern:

Thank you for the opportunity to comment on Docket No. APHIS-2006-0024, a proposed rule to amend the Animal Welfare Act regulations by:

- (1) adding a minimum age requirement for the transport in commerce of all covered species;
- (2) amending the current regulations pertaining to the shipment of underage animals to research facilities; and
- (3) adding a new requirement when covered animals are shipped for the purpose of receiving medical attention.

After a careful review of this proposal, which appeared in the May 9, 2008 edition of the *Federal Register* (Volume 73, Number 91, pages 26344-26349), the National Association for Biomedical Research (NABR) strongly urges the USDA to withdraw this proposal. As currently written, this proposed rule does not provide a basis for meaningful comment. We respectfully request the Agency develop a more focused proposal that takes into account the biological requirements of the species involved. We further request the Agency provide documentation on existing failures in transportation of regulated species below eight weeks of age. NABR and its members are willing to work with the Agency in gathering the necessary information to develop such a proposal. The major concerns raised by the language in the existing proposal are enumerated below.

Background

The Agency's position is that its regulations governing the minimum age of animals transported in commerce should be uniform. USDA regulations currently contain minimum age requirements for dogs and cats transported in commerce, and the Agency proposes to apply these same requirements to all covered animals. In principle we agree all covered animals should be governed by species-appropriate requirements.

We do not agree that particular requirements appropriate for dogs and cats will be appropriate for all covered species. The biological requirements of the many species covered by the Act vary. Therefore, it is not possible to promulgate a uniform set of rules without imposing arbitrary requirements. Furthermore, we do not believe the Agency has provided adequate justification, based on available scientific data and husbandry practices, to impose the additional requirements outlined in this proposed rule. Sixty percent of the covered species used in research in 2006 were species that are routinely weaned and shipped prior to eight weeks of age (guinea pigs, hamsters or rabbits). If one included other frequently-used species such as gerbils, ferrets and pigs, this percentage would be even greater. Furthermore, guinea pigs, hamsters, gerbils and rabbits used in research are maintained and ordered based upon body weight and not by specific age.

To adopt the same standards for the majority of animals used in research is not in keeping with the long established and accepted practices of veterinary experts who work in this field. Other federal agencies have recognized that regulations or standards based on uniform age requirements are not always appropriate. For example, the Food and Drug Administration (FDA) Guidelines for Conducting Toxicity Studies (<http://www.cfsan.fda.gov/~redbook/red-ivb1.html>) require, "Testing should be performed on young animals, with dosing beginning as soon as possible after weaning and following an acclimation period of at least 5 days. Dosing of rodents should begin no later than 6 to 8 weeks of age. When dogs are used, dosing should begin no later than 4 to 6 months of age." We believe that this language

underscores the need for the regulations to be consistent with the biologic differences in the covered species and serves to support our belief that adopting a single age-based standard for all species is scientifically inappropriate.

The proposed rule does not provide any background or an underlying rationale for imposing uniform requirements while ignoring species-specific biological requirements. Without knowing the Agency's perceived basis for proposing these new regulations, it is difficult to provide meaningful input. Have there been past enforcement issues that have prompted this proposal? The Agency references past enforcement issues but provides no details on what such issues entailed and how they are relevant to this proposal. Is this proposed rule based on acknowledged animal care principles documenting that transportation of more than two hours is stressful to unweaned animals given that the nursing interval for many species is much greater than every two hours? What is the source for the animal care principles embodied in this proposed rule?

Based upon the information provided in this proposal, it would appear the Agency is unaware how many animals of any species under eight weeks of age or unweaned are currently shipped to research institutions, and thus has not documented a need to increase the amount of paper work that is currently required.

Transportation Plan (required for exception to new requirements)

Since all use of covered species in research, teaching or testing must be described in a specific IACUC-approved research protocol, adding the proposed language regarding a protocol to existing requirements is unnecessary. In addition, it is unclear who would be responsible for the development of the proposed transportation plan. In the current Standards the language pertaining to **Consignments to carriers and intermediate handlers**, the responsibility for developing the paper trail falls to the consignor. The transportation plan contained in this proposal would appear to require the consignee to assume this responsibility, yet they would not have specific transportation details which could easily change if there was a delay in the approval process. If the responsibility for the transportation plan falls to the commercial supplier, large commercial breeders of commonly used small mammals, in our analysis, could each be responsible for preparing and executing more than 5000 of these plans per year. The process of review by the USDA at regional locations holds open the potential for delays in approval because of the need to review information at the receiving institution or disagreements regarding the appropriateness of arrangements, inconsistently applied standards or institutional justification of need to use animals less than 8 weeks of age. It is also unclear as to why such a plan would require more than the signature of the attending veterinarian, who is required by regulations to oversee the adequacy of the veterinary care provided and other aspects of animal care and use. It is also not clear what is meant by the receipt of "written approval" before animals could be transported. Since the request can be made using either e-mail or facsimile to avoid delay, it does not seem logical that an approval could not be transmitted in the same manner. Even with all components of the transportation plan in place, it still will not avoid delays, accidents, misrouting, or other uncontrollable events which this proposal seeks to address. Given the extremely low transportation failure rates for regulated and non-regulated species commonly used in research cited in a recent National Academies of Science report on transportation, it is unclear how the proposed transportation plan process with its additional complexities and potential delays will improve the process and safety for regulated research animals.

NABR believes there are many inconsistencies in this proposal. For example, the proposal would require a transportation plan for animals under the age of eight weeks that are shipped to a licensed veterinarian to receive medical care. Given the basic premise of this proposal to help ensure humane treatment of these animals, it is unclear as to why a plan would be required for animals shipped outbound, but not for those that were being returned. If there is indeed a need for such a plan, would not that need be doubled by round trip shipment?

Executive Order 12866 and Regulatory Flexibility Act

Since the majority of the covered species currently shipped to research facilities have a biological weaning age of less than eight weeks of age, we have serious reservations about the regulatory flexibility analysis that was conducted. The proposed eight week minimum age for animals would have a major impact on the providers of those species for research and would require a significant increase in the administrative cost of obtaining those animals.

Benefits and Cost of the Rule

We find it puzzling how the Agency determined this proposed rule would reduce the frequency of illness and death of young animals in transportation, given that the agency does not currently know how many licensed animal dealers transport underage and unweaned animals, much less how many animals are involved. In fact, the benefit to dogs and cats has not been documented. How one would calculate the benefits when the current costs are unknown is unclear.

In its analysis, the agency provided some examples of proposed increased costs. One of those analyses involved guinea pigs that were found to sell for \$30.00 and cost \$1.00 per day to feed (NOTE: These costs are not at all reflective of the current average selling price or fully loaded maintenance costs which are considerably greater than when the data quoted by the Agency was compiled). According to the Guinea Pig Fact Sheet contained on the USDA's Animal

Welfare Information Center (AWIC) website, the weaning age of a guinea pig is 14-21 days. While this weaning range has been quoted in a few publications, guinea pigs are most commonly weaned by 5 to 14 days of age with no impact on their welfare. Under the proposed new weaning age of eight weeks, the additional cost of feeding a guinea pig would add from \$35.00 to \$42.00 (based on the agency's numbers) to the sale price of each animal. This would more than double the cost of the animal, not to mention increasing the cost of shipping much larger animals. Having consulted with experts providing purpose bred guinea pigs for biomedical research we believe the figures used in the analysis do not accurately reflect the real impact on animals used in research. Purpose bred guinea pigs are raised in barrier facilities, which adds significantly to the daily cost of maintenance. In addition, requiring that these animals be maintained by the breeder for an additional 5-6 weeks would require a significant investment in additional equipment and facilities. Shipping costs (transportation plus additional containers) would double since the number of 8-week old animals that could be safely transported in a container while conforming with existing transport guidelines would be half the number of younger animals.

Assessment of Alternatives

Given the lack of justification for the proposed change in the current language and given that the proposed language is inconsistent with the known biological needs of the majority of the covered species used in research, we believe the first alternative identified by the Agency (i.e. no change to the existing rule) is justified at this time.

NABR appreciates the opportunity to comment on the proposed changes in the current regulations pertaining to the minimum age requirements for transport of animals covered under the Animal Welfare Act.

The National Association for Biomedical Research (NABR) is the only national, nonprofit organization dedicated solely to advocating sound public policy that recognizes the vital role of humane animal use in biomedical research, higher education and product safety testing. NABR's membership is comprised of over 300 public and private universities, medical and veterinary schools, teaching hospitals, voluntary health agencies, professional societies, pharmaceutical companies and other animal research-related firms.

Respectfully,



Mary F. Hanley
Executive Vice President