March 3, 2008

Docket No. 99-014-2
Regulatory Analysis and Development
PPD
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD  20737-1238

To Whom It May Concern:

Thank you for the opportunity to comment on Docket No. 99-014-2, a proposed rule published in the January 3, 2008 Federal Register, outlining proposed changes in the current regulations and standards covering the shipment of animals (except marine mammals) regulated under the Animal Welfare Act. The specific citation is [Docket No. 99–014–2] RIN 0579–AC41, Animal Welfare; Climatic and Environmental Conditions for Transportation of Warmblooded Animals Other Than Marine Mammals.

As stated in the Federal Register notice, this is a withdrawal and re-proposal of a proposed rule originally published June 7, 1999 for which 19 comments were received. At that time,APHIS proposed that acclimation be certified by the owners. This reproposal would make  acclimation certificates for live animals other than marine mammals unnecessary. It would also remove the current ambient temperature requirements for various stages during the transportation of covered species and replace those requirements with a single performance standard under which the animals would be transported under climatic and environmental conditions appropriate to their welfare.

Acclimation Certificates

Current regulations require that ambient temperatures be maintained within certain ranges during transportation, but animals may be transported at ambient temperatures below the minimum temperatures if their consignor provides a certificate signed by a veterinarian certifying that the animals are acclimated to temperatures lower than the minimum temperature. It is interesting to note, that the regulations do not provide any such mechanism for certifying acclimation to temperatures above the maximum stated limit. Elevated environmental temperatures are commonly encountered in the continental US.
While acclimation certificates would seem to be an appropriate way to allow animals that are acclimated to temperatures below the stated minimum to be transported, the basis for determining whether the animals are adequately acclimated is hard to both establish and then verify. Animals can make morphologic, physiologic and behavioral adaptations to temperatures outside of their thermoneutral zones and the concept of acclimation is, in fact, a valid one. That said, in our opinion there is no way to administer such a certification program in a manner that assures an animal’s fitness to travel under any set of prescribed conditions including within current USDA temperature conditions. For this reason, we support the USDA’s efforts to eliminate acclimation certificates.

Eliminate Temperature Guidance

The proposed rule would amend 9 CFR Parts II and III by eliminating specific temperature guidance in sections for all covered species except marine mammals. It would eliminate standards during transport and put in its place a “performance standard” in Section 2.131(f) which would read as follows:

“(f)(1) Transportation of all live animals shall be done in a manner that does not cause overheating, excessive cooling, or adverse environmental conditions that could cause unnecessary discomfort or stress. When climatic or environmental conditions, including temperature, humidity, exposure, ventilation, pressurization, time, or other environmental conditions, or any combination thereof, present a threat to the health or well-being of a live animal, appropriate measures shall be taken immediately to alleviate the impact of those conditions. The different climatic and environmental factors prevailing during a journey shall be considered when arranging for the transportation of and when transporting live animals. Corrections may include, but would not be limited to:
   (i) The temperature and humidity level of any enclosure used during transportation of live animals must be controlled by adequate ventilation or any other means necessary;
   (ii) Appropriate care must be taken to ensure that live animals are not subjected to drafts;
   (iii) Appropriate care must be taken to ensure that live animals are not exposed to direct heat, such as placement in direct sunlight or near a hot radiator;
   (iv) Appropriate care must be taken to ensure that live animals are not exposed to direct sources of cold; and
   (v) During prolonged air transit stops in local climatic conditions that could produce excessive heat for live animals held in aircraft compartments, the aircraft doors shall be opened and if necessary ground equipment shall be used to control the condition of the air within compartments containing live animals.

(2) In order to determine what climatic and environmental conditions are appropriate for a live animal, factors such as, but not limited to, the animal’s age, type or breed, physiological state, last feeding, and acclimation shall be considered when such information is available.”

The concept of using a performance standard was suggested by 1 of the 19 responses that were initially received on the original proposal to modify the current regulations. The present proposal to substitute this “performance standard” for existing specific temperature guidance raises the question as to whether there have been problems involving the implementation of the existing language that would warrant the agency to follow the advice of one commenter. The commenter proposed that the acclimation certificate be eliminated and that the USDA add to the current temperature requirements a performance standard stating that “…at no time may an animal be exposed to a combination of temperature, humidity, and time that would pose a threat to the animal’s health and well-being.” That commenter’s proposed language was drawn from existing language contained in Section (e) of 2.132 of the regulations.
The use of performance standards has gained increasing acceptance by regulators and oversight bodies developing guidance for the humane care and use of animals under a variety of circumstances. *The Guide for the Care and Use of Laboratory Animals* produced by the National Academy of Sciences is an example of such a guidance document. Temperature standards contained within the present regulations that this proposal addresses are commonly referred to as “engineering standards” in that they set forth precise temperatures under which it is assumed that animals of a particular species can be transported in safety. Deviation from these temperature ranges no matter how slight or for what period of time could be interpreted as a violation of the regulations by the USDA. However, the regulations currently provide some flexibility by allowing animals to be held outside these ranges for defined periods of time.

These engineering standards assume that there is a high degree of certainty that these temperatures are the only safe and acceptable range under which animals can be transported and that no other factors would modify these ranges. Built into the assumption underlying the existing engineering standards within the current regulations is an acknowledgement that there are times when these temperature ranges may be exceeded but in such instances it is extremely unlikely there will be any adverse effects on the health of the animal. Hence, there are times varying from 45 minutes to 4 hours where these ranges can be exceeded and that there can be more than one such period during a journey. The current proposal does not provide any data supporting the proposition that the present system is inadequate and has resulted in death or harm to animals being transported. If the agency has data on the number of animal shipments resulting in death or harm, this information should be provided so the community has the opportunity to comment on such events. The agency should include information on the number of animals by species that died or were injured as a direct result of these periods of variance. Data on the total number of animals shipped would also be useful in evaluating the adequacy of the present system.

A performance standard, in contrast to an engineering standard, describes in sufficient detail the outcome to be achieved. Reinforcing that standard is a stated or implied set of factors and measures that can be used to determine the adequacy of the outcome achieved as well as the appropriateness of the methods used. The adoption of a performance standard acknowledges that not all situations are the same and that a single prescribed method will not address all situations.

The performance standard as presented in the current proposal suffers from two significant deficiencies. As currently written the proposal states, “Transportation of all live animals shall be done in a manner that does not cause overheating, excessive cooling, or adverse environmental conditions that could cause unnecessary discomfort or distress. When climatic or environmental conditions, including temperature, humidity, exposure, ventilation, pressurization, time, or other environmental conditions, or any combination thereof, present a threat to the health or well-being of a live animal, appropriate measures shall be taken immediately to alleviate the impact of those conditions.” The first sentence requires a stated outcome that is difficult, if not impossible, to measure. It is generally accepted that transportation of animals is likely stressful and associated with some level of discomfort. The measures for these, however, in the various species to which the proposed performance standard is suppose to apply cannot be readily determined during the actual transportation process during which time such evaluations would have to be made. Moreover, there are no generally accepted measures for assessing discomfort or distress even in controlled conditions. The only potential clinical measure would be to extrapolate conditions for humans to animals and even so there is tremendous variation between individuals. Modifiers such as excessive, adverse or unnecessary would also likely be interpreted differently by the variety of individuals participating in the animal transport process as well as those USDA VMOs charged with oversight. It is also unclear what is meant by the term “exposure.”
The second sentence in this “performance standard” is more focused, but nevertheless remains ambiguous with respect to requirements for understanding the limits and responsibilities of those trying to follow the regulations or to enforce them. It is not clear in the proposal whether the agency is attempting to primarily address exposure of animals to direct sunlight, high winds, and precipitation. The proposal should be modified to include more objective standards for addressing the concerns intended to be cured by this proposal. As currently written the proposal is open to subjective interpretation by both the regulated community and regulatory enforcement personnel.

Transportation always carries with it some risk to an animal’s health or wellbeing. It is the magnitude of the acceptable risk and the availability of practical mechanisms to mitigate such threats that are important in determining whether unreasonable risks are present during transportation. Organizations such as the International Air Transport Association (IATA) provide detailed guidance to shippers, carriers and intermediate handlers on appropriate conditions for the transport of animals, but even these cannot guarantee there is no threat to health or wellbeing.

We do not believe the agency has adequately justified the need for his proposal. However, we do believe in most situations the use of performance standards is the best approach to addressing these issues. If a new performance standard is adopted to address transportation issues, we believe it must be much more specific and measurable. At a minimum, the agency should include safe harbor provisions outlining actions constituting evidence that a good faith effort was made to assure the appropriate levels of control were exercised over the animal’s environment to minimize the threat to its health and wellbeing. We also believe the agency should provide specific examples of situations that would not, per se, constitute a violation of these new regulations. For example, since accidents occur in transportation of people, as well as animals, would such an accident be a violation even if there were no way to have foreseen or prevented it?

Given the restrictions currently in place for the USDA in terms of limited personnel and funding, it is unlikely that airports, holding facilities, aircraft, land carriers, and other components of the animal transportation network will be frequently inspected. The present system of investigating deaths or illness in animals during shipping by examining records of institutions or individuals receiving animals as consignees of the animal transportation process would likely continue to be used as the principal means of oversight along with any carrier’s records. Investigation of such adverse events under the proposed performance standard would be no better than the present temperature requirements in assigning responsibility for the death or injury of the animals.

**Relative Humidity**

In the new section 2.131(f), there are five proposed corrective actions described. The first of these suggests that temperature and relative humidity of any enclosure used during transport of live animals must be controlled by adequate ventilation or any other means necessary. While it is possible to provide some level of control of temperature of enclosures such as holding facilities, aircraft cargo compartments, etc., relative humidity control is quite another matter. Relative humidity levels cannot be tightly controlled even within the passenger compartments of aircraft, let alone cargo holds. The energy requirements and equipment necessary for tight control of relative humidity are not compatible with air cargo. Similarly, ground transportation vehicles are not capable of tight relative humidity control since they require intake of outside air on a continual basis and as with most passenger cars have no real means of adjusting relative humidity with any precision, especially when those levels in the outside environment are at extremes. Placing such a requirement on transportation systems would effectively place them in violation of
regulations and would cause many carriers to avoid such a risk and refuse carriage which would ultimately limiting commerce.

Advice on corrective measures must be specific when using words such as enclosure. For example, it is unclear whether the term enclosure is in reference to the primary enclosure (shipping container) or secondary or tertiary enclosures (e.g., rooms, buildings, etc.). Similarly, the judgment of whether ventilation is adequate or not would have to be done at the time of transportation, and there is no appropriate standards or means of assessment as to adequacy.

**Eliminating Drafts**

The second control example states “Appropriate care must be taken to assure that live animals are not subject to drafts.” Both animals and humans can detect air movement. The concept, however, of draftiness or drafts is purely a human-oriented concept. Key peer-reviewed papers on the subject base their modeling of drafts on human comfort which is inextricably associated with an assessment that is subjective and varies substantially between individuals. Drafts are defined in this context based upon point velocities of air measured at various locations surrounding and over body surfaces on test subjects struck by the air. There are many mitigating factors including presence or absence of hair, presence or absence of clothing, types of clothing, temperature and relative humidity of the air, diffuser type and location, etc. There is no clear evidence documenting that the presence or absence of drafts as being a factor in health status or, for that matter, in wellbeing in a manner that could be generally applied across man let alone all of the species of animals covered by the proposed change in the existing regulations. Moreover, since point velocities vary according to the position of the animal as well as the container, container design, secondary enclosure design, diffuser type and design, and a variety of other factors, the measurement in one point could fall outside of an arbitrary specification but a similar measurement in another point in the same container would be within specification. Overall, this control example is not adequately justified and would effectively eliminate remedies such as using fans or other forms of mechanical ventilation to mitigate areas with either elevated or low temperatures.

**Direct Heat**

The third correction or caution statement, “Appropriate care must be taken to ensure that live animals are not exposed to direct heat, such as placement in direct sunlight or near a hot radiator”, lacks both time and distance considerations. This requirement would depend upon how one evaluated this area, and therefore will likely be a continual source of disagreement between USDA VMOs and carriers.

**Exposure to Cold**

The fourth example provides the admonition that direct exposure to sources of cold are also not appropriate. Again, in many sources of carriage of animals, cool air is discharged into the secondary enclosure and is mixed with warmer air. The admonition of not being exposed to direct sources of cold would depend upon how one evaluated this area, which again will likely result in a source of disagreement between USDA VMOs and carriers.

**Aircraft Compartments**

Example five states that “…local climatic conditions that could produce excessive heat for live animals held in aircraft compartments, the aircraft door shall be opened and if necessary ground
equipment shall be used to control the condition of the air....” This provision suggests that either
the engines would have to be left running to provide conditioned air or that separate air handling
equipment would have to be available and compatible with the aircraft so as to keep the
compartment conditioned while the door is either left open or closed. Inclusion of such a specific
requirement/consideration appears to address an unlikely set of circumstances since animals
would likely be unloaded from compartments according to existing IATA live animal regulations.
One must also wonder whether transport would be denied by the carrier under these stated
conditions if an intermediate stop was necessary, especially if substantial expense would be added
to meet this condition by the carrier for a single container of animals.

Additional Acclimation Factors

Lastly, there is a statement made in the proposal requiring that factors such as but not limited to
the animals age, type of breed, physiological state, last feeding, and acclimation should be
considered when such information is available. It is unclear how this guidance would be used as
stated in the proposal given that there is almost no applicable information available on the effects
of these variables in the peer-reviewed literature for the many species that would be covered
under this proposal. It is also unclear as to why the acclimation status was included since the
changes proposed would drop the requirement for a certificate of application.

Subjective Clinical Observations

In addition to our specific concerns with the proposed language specified above, we object to the
following statement which was made on page 415 of the Federal Register notice: “If we suspect
that climatic or environmental conditions have not been properly maintained, an inspector will
observe the animal for clinical signs of exposure to adverse conditions, examine the enclosure,
and record the ambient temperature.” Given the fact that the inspector will be using his or her
professional judgment under the proposed performance based standards, the use of subjective
clinical observations as opposed to objective clinical measurements could lead to as many
interpretations as there are inspectors.

While the proposed use of performance based standards for assessing the appropriateness of
environmental conditions encountered by animals that are being transported would appear to be a
positive step forward, in its present form it is a step backward in that it will likely restrict
transportation due to the lack of clarity coupled with standards that are not sufficiently defined
and hence open to conflicting interpretation.

We urge the USDA to withdraw this proposal and analyze existing failures in transportation of
regulated species in order to develop a more focused proposal for change in light of the total
number of animals being transported. In the end, any such proposal should be focused on
guidance that is practical and capable of functioning within existing systems of transportation.

Finally, if the language currently contained in Sect 2.131(e) is applicable to the transportation of
animals why would it not be applicable for the housing of animals? It would seem that the use of
performance standards as it relates to the control of temperature and humidity within housing
facilities would be much easier to implement than it would be for the varied conditions
encountered when shipping animals.

NABR appreciates the opportunity to comment on the proposed changes in the current
regulations and standards that cover the shipment of animals (except marine mammals) 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