Docket No. APHIS -2006-0159
APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Handling of Animals; Contingency Plans

To Whom It May Concern:

Thank you for the opportunity to comment on Docket No. APHIS-2006-0159, a proposed rule to amend the Animal Welfare Act regulations by adding requirements for contingency planning and training of personnel by research facilities and by dealers, exhibitors, intermediate handlers, and carriers. The proposed plan would include:

(1) Identification of situations requiring a contingency plan
(2) An outline of specific tasks required to be carried out in response to the identified emergencies
(3) Identification of a chain of command and who will be responsible for fulfilling the tasks in this plan, and
(4) Addressing how the response and recovery will be handled in terms of materials, resources and training.

After a careful review of this proposal, which appeared in the October 23, 2008 edition of the Federal Register (Volume 73, Number 206, pages 63085-63090), 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 providing more details on the specific content that must be included in the required contingency plan. Additionally, we request that the regulations address any conflict resulting from an intervention in the execution of a contingency plan by a higher statutory authority, state or federal, responsible for the disaster area. We further request the Agency provide information on the number of animals that have been negatively impacted by disasters or emergencies in facilities covered by this proposed rule change. NABR and its members are willing to work with the Agency in gathering this information. The major concerns raised by the language in the existing proposal are enumerated below.

Summary

The Agency is proposing to add requirements for contingency plans for intermediate handlers and carriers. Should a more focused proposal be reissued, we request it not
include intermediate handlers and carriers. The very nature of their activities coupled with the current requirements for transportation of covered species contained in Part 3 makes it unlikely carriers and intermediated handlers would have control over animals during the type of emergency or disaster it appears these plans are intended to cover. Specifically, NABR is concerned, that depending upon how one interprets the current proposal, carriers and intermediate handlers could either be extensions of the research or breeding facility or independent agents. It is unclear whether carriers would need to file separate disaster plans to cover the portion of the time they handle animals or whether it would be the responsibility of the research institution or breeding facility to provide such disaster plans. In either case, the practicality of extending this requirement to carriers is very questionable and could easily result in the loss of access to air and ground transportation. It also begs the question of whether the carrier possesses the legal authority to implement a disaster plan involving customer-owned animals without the customer’s consent.

SUPPLEMENTARY INFORMATION

Background

The Agency’s position is that as a result of the events experienced during the 2005 hurricane season all licensees and registrants should be required to develop a contingency plan for all animals regulated under the AWA in an effort to better prepare for potential disasters. While NABR believes contingency plans are an important component of a well-managed animal care and use program, we are concerned the intent of the Agency is not clear in the proposed language. If the intent behind the proposed rule on contingency plans is to better prepare facilities for disasters, while simultaneously allowing them to formulate a plan that best suits their needs, then the lack of specific details as to what elements must be included in all contingency plans is appropriate. However, if the intent of agency is to hold facilities accountable for following the letter of those plans, regardless of the nature of the disaster, then the lack of specific detail is problematic and unacceptable.

The first component of the plan is the identification of events that would trigger the need for a contingency plan, including emergencies such as electrical outages, faulty HVAC systems, fires, and animal escapes, as well as natural disasters the facility is most likely to experience. While the assessment of risks related to potential emergencies and the resulting plan that would be developed as result of that assessment is relatively straightforward, the same cannot be said when attempting to develop plans to respond to natural disasters. NABR believes regulatory language addressing these two disparate events must recognize the difference between emergencies and natural disasters and should not hold the facilities to the same level of accountability for contending with these events.

The second component of the plan is to outline specific tasks required to be carried out in response to the identified emergencies including, but not limited to, detailed animal evacuation instructions or shelter-in-place instructions. The requirement that this part of
the plan be in an outline format implies such a plan would not require a great deal of
detail and thus be open to subjective interpretation by both the regulated community and
the regulatory enforcement personnel. NABR is particularly concerned about the need for
detailed evacuation or shelter–in-place instructions since facilities working in a Good
Laboratory Practices (GLP) environment, and facilities in which breaches in the health
status of animals or their environment would negate the animal’s usefulness, may have no
choice but to euthanatize animals in the face of a disaster. It is unclear whether this
practice would be acceptable.

The third component involves identifying a chain of command by name or by position
title of those who will be responsible for fulfilling these tasks, which is clearly an
essential component of such a plan. NABR’s concern is the highly prescriptive
requirements for training individuals responsible for carrying out the plan. As worded,
the training requirements appear to apply to all employees, rather than only to employees
identified by the facility as responsible for implementing the plan. It is extremely unlikely
that a new employee would be given such an important responsibility. As a result, the 30
day requirement for training such individuals seems both unnecessary and not in keeping
with lack of specificity in the rest of the plan.

The fourth component of the plan includes addressing how response and recovery will be
handled in terms of materials, resources and training needed. NABR is concerned about
this component as it relates to the requirement that the contingency plans would have to
be in place within 180 days of the effective date of the final rule. If this component of the
plan identifies materials and resources not currently available within a facility, does the
180 day time frame mandate the acquisition of materials and resources by the
implementation date? For facilities without existing contingency plans and the necessary
materials and resources to implement them, acquiring such resources within such a short
time period would be extremely difficult if not impossible.

NABR would like to emphasize that the execution of any contingency plan could be
greatly impacted by the intervention of a higher regulatory authority with responsibility
and control of the area. At a minimum, the proposed rule should be revised to include
language that will relieve the regulated entity of its responsibilities should a higher
emergency response authority intervene and make it impossible for the regulated entity
to follow its plan as specified in the existing regulations.

**Executive Order 12866 and Regulatory Flexibility Act**

NABR has reviewed the Preliminary Regulatory Impact Analysis and Initial Regulatory
Flexibility Analysis and has several concerns about the information contained in that
document.

**Introduction** - As part of the analysis, assumptions are made as to how many
regulated animals were impacted by the events surrounding hurricane Katrina. Since the
total number of regulated species reported to have been used in the entire state of
Louisiana for FY 2005 is less than 13,000, the conclusions reached in the analysis are open to question.

**Proposed Rule and Contingency Plan Components** – In this section the Agency indicates that all potential emergencies be addressed no matter how remote the possibility of the emergency arising. This requirement is not consistent with the fundamental principles of a risk assessment based management system and appears more in line with a risk avoidance management system. If this is indeed the case, the estimated impact in terms of both time and cost to prepare the proposed contingency plan has not been accurately assessed. Also included in this section are some suggested general steps that should be taken by facilities in the development of a contingency plan. Had similar information been provided in the Background section of the notice in the *Federal Register*, the regulated community would be able to provide more substantive comments.

**Specific Facility Considerations** – In the subsection *Research Facilities*, reference is made to informing disaster mitigation agencies to ensure that animals are cared for after evacuation. It is unclear to NABR which agencies could provide support to ensure the continued care of animals maintained in research facilities. Since moving animals on experimental protocol could serve as a significant non-experimental variable and thus negate the future use of those animals on the research project, the only option available may often be euthanasia. The fact that this is not recognized in the analysis is of concern to NABR as it relates to the Agency’s understanding of the complexity of managing animals maintained in research facilities.

**Expected Benefits and Costs of the Rule** – This section contains little specific information that could have formed the basis for a realistic cost benefit analysis.

**Significant Alternatives to the Rule**

NABR agrees with the Agency that the submission of contingency plans to APHIS for review as required for marine mammal facilities is not a cost effective option and therefore should not be pursued.

**Summary**

NABR agrees that preparedness for disasters can reduce harm to animals but may not reduce the loss of life. The fact euthanasia may be the only option in the event of a major disaster and thus be a key component of a contingency plan must be recognized by the Agency. NABR also questions the need to train all facility employees as opposed to training those identified with responsibility for implementing the plan. We also question the assumption there will be minimal cost involved with the development of the proposed contingency plans. To be effective such plans may require the availability of resources currently not in place and thus result in major costs to the research or breeding facility.

**Part 2 – Regulations**
While NABR believes that the current proposal should be withdrawn and a more focused proposal developed that will provide a basis for meaningful comment, we offer the following comments.

In 2.38, (1),(1) the requirement that a plan would have to be followed would appear to imply that failure to do so would result in a facility being found to be in noncompliance regardless of nature of the disaster and the circumstance that surrounded the facility’s inability to follow to the letter their contingency plan. We would suggest that the word “follow” be replaced by the word “implement.” The language contained in parenthesis appears to be in conflict with language contained in the Preliminary Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis, which indicates that all potential emergencies be addressed no matter how remote the possibility of the emergency arising. The same can be said for the language contained in 2.38(l),(1),(i).

In 2.38, (1),(1),(ii), we recommend that the phrase “backup sources of” be deleted and that the phrase “as described in the contingency plan” be inserted after the phrase “as well as sanitation, ventilation, bedding, veterinary care, etc.” We believe this is necessary because all of the components described in 2.33,(b) for veterinary care may not be possible to maintain during a disaster.

In 2.38, (1),(2), we recommend that the first sentence be deleted and the phrase in brackets be moved to appear after the word APHIS in what is now the second sentence. This is necessary because if a contingency plan requires the acquisition of equipment or alteration of existing support services, the 180 day time frame may not be achievable.

In 2.38, (1),(3), we recommend deleting the second and third sentences. The very prescriptive nature of these two sentences is not consistent with training requirements in other sections of the regulations.

In 2.134 similar changes as recommended above should be made.

NABR appreciates the opportunity to comment on the proposed rule to amend the Animal Welfare Act regulations by adding requirements for contingency planning and training of personnel by research facilities and by dealers, exhibitors, intermediate handlers, and carriers. We respectfully request this proposal be withdrawn.

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,

Matthew R. Bailey
Vice President