

2 November 2000

Docket No.00-005-1  
Regulatory Analysis and Development  
PPD  
APHIS  
Suite 3C03  
4700 River Road  
Unit 118  
Riverdale, Maryland 20737-1238

Dear Sirs,

The Ornithological Council appreciates the opportunity to comment on the proposed Definitions for and Reporting of Pain and Distress, *65 FR 42304*). The Ornithological Council consists of ten leading scientific ornithological societies in North America that together have a membership of nearly 6,500 ornithologists. It is our mission to provide scientific information about birds to legislators, regulatory agencies, industry decision makers, conservation organizations and others, and to promote the use of scientific information in the making of policies that affect birds. We also represent the concerns of ornithologists to the regulatory agencies and other organizations that authorize research activities involving wild birds. Our comprehensive, peer-reviewed publication entitled *Guidelines to the Use of Wild Birds in Research*, which sets out the profession's standards for research methods has been distributed to the members of the ornithological societies, to the US Fish and Wildlife Service (the Service), to the Biological Resources Division of the US Geological Survey, and to many other government agencies and researchers. This publication emphasizes the legal and ethical considerations that form the foundation for both permit requirements and acceptable research methods.

Defining the term “distress” seems to us to be an exercise in animal welfare philosophy rather than in science. It would not benefit research animals, investigators, or the Institutional Animal Care and Use Committees that are required to report to APHIS annually on the effects of research activities on animal subjects. Our primary concern, however, is that the animal welfare laws and regulations of this country, which were never intended to apply to research on wildlife in their natural environment, are increasingly extended to that type of research without regard to the fundamental differences in laboratory-based biomedical research and field research on the behavior and ecology of wild animals. We are concerned that in defining terms under the Animal Welfare Act, this distinction is again overlooked.

### Potential effects on wildlife biology

We are concerned that any definition or alteration of threshold reporting level take into account the differences between laboratory and field investigations. Although the Animal Welfare Act does not, by its terms, apply to field studies, the term field study is defined in such a way as to include many, if not most, research activities involving wild animals in their natural environments. Field studies are not exempt from IACUC scrutiny if the research involves, “harm, invasive procedures, or material alteration of behavior.” Due to the lack of definition of those terms, or because Public Health Service Policy on Humane Care and Use of Laboratory Animals covers all activities involving live vertebrates, IACUCs routinely scrutinize proposals involving field studies. However, field biology is inherently different from laboratory studies. In most laboratory studies, animals are used as test subjects to determine the effect of stimuli, drugs, or surgical or behavioral procedures. The animals are used as surrogates for humans. In virtually all field studies, it is the animals themselves that are the objects of interest.

Wild animals may be more sensitive to capture and manipulation than their captive-raised counterparts. Even if distress could be quantified by reference to heart rate, respiratory rate, or hormonal production, it would be impossible to measure physiological responses in the field. Researchers simply cannot carry that much equipment and devote that much time to such techniques. Furthermore, it would increase the time required to hold and manipulate the animal and would, therefore, *increase* the effect of the research methodology on the animal. The result would be inapposite to the purpose of the AWA, which is to reduce the unpleasant effects of research on animal subjects.

It is difficult, if not impossible, to observe the post-release behavior of wild animals. So, it would be impossible to know if there was a disruption of feeding or grooming behaviors, which the National Research Council definition would include as a sign of distress.

*Therefore, we respectfully request that any definition of distress expressly exclude research on wild animals conducted in the natural environment of those animals.*

### Undefined subjectivity vs. defined subjectivity

The Animal Welfare Act exists precisely because it is assumed that animal subjects experience some unpleasant sensations - both physical and psychological or emotional - during experimental procedures. The AWA requires that animals be handled in such a way as to minimize or eliminate those unpleasant sensations. It is true that well-defined terms enhance compliance and enforcement. Indeed, we have urged APHIS to define the terms “invasive procedure,” “harm,” and “material alteration of behavior” in the definition of the term “field study.” However, the term “distress” seems to us to require qualitative and/or quantitative interpretation of what is essentially a subjective, human concept. This subjectivity cannot be eliminated by imposing further human definitions. Further, application of any criteria that might be developed is impractical, if not impossible.

We see no practical, realistic way of defining distress for the following reasons:

1. *An adequate definition would require the elimination of subjective assessment.* The human assessments of the responses of animals are subjective. Some humans, especially those unaccustomed to working with live animals, assume that every vocalization suggests that the animal is experiencing intolerably high levels of negative sensations. A human who is afraid of injections will assume an animal is in distress when injected. To eliminate this subjectivity completely, it would be necessary to monitor the heart rate, pulse, brain activity, and steroid levels of every animal in every procedure. Requiring these measurements would make research prohibitively costly and time-consuming.
2. *The boundary between “stress” and “distress” is inherently subjective.* Although it is highly impractical, one could measure heart rate, pulse, and the presence of stress hormones during the procedure. However, an elevated heart rate or pulse and the production of stress hormones are not the equivalent of distress. Distress is not a discrete state. There is a continuum of stress that may result from a given procedure, and where stress ends and distress begins is an unanswerable question.
3. *An adequate definition would have to recognize differences among individuals.* Responses vary significantly among individuals. Some will exhibit behaviors indicative of discomfort (such as vocalizations or efforts to escape) simply because they are held by humans, even when no procedure is taking place. Others will sit quietly, but may be undergoing significant discomfort. Recognizing this difference complicates the reporting requirements significantly. Is the reporting requirement triggered if only one individual responded in a way that has been defined as distress?
4. *Any adequate definition of distress would have to species-specific.* Responses vary significantly among species. For instance, birds in pain show varying responses. They tend to change their behavior, but there is variation among species. Possibilities include - tonic immobility, decreased social interactions, apprehension, decreased grooming, "fluffed feathers," slight alteration in posture/ perching position, or absence of normal behaviors. There may be increased or decreased vocalization. Stimuli that are painful to people may not be painful to birds. Some individual birds are more or less stoic than others. Some birds, like other species, may not manifest any overt signs until the negative stimuli reach a certain level.

Although we oppose this effort to define the term “distress,” we suggest that if APHIS chooses to define the term “distress,” specific, objective (quantifiable) criteria be stated as those that must exist to trigger the reporting requirement. Examples would include weight loss of a certain percentage of total mass over a certain period of time in the absence of physiological causes such as illness; self-mutilation over a certain period of time rather than an isolated episode, or tonic immobility. Even these indicia, however, may be misleading. For instance, after being banded, some birds fly off immediately upon release. Others will sit motionless on an open hand or nearby perch for many minutes. Also, we often do not know what certain behaviors indicate. For instance, it is assumed that feather-plucking in birds results from psychological distress. However, in a test of feather-pluckers and non-feather pluckers, both exposed to the same negative stimuli (deprivation of dust-bathing), the duration of tonic immobility was significantly longer in non- feather pecking than in feather-plucking birds ( $P < 0.001$ ), and significantly more

induction periods were needed to induce the state of tonic immobility in feather-pecking birds ( $P < 0.05$ ). Feather-pecking birds and non-feather pecking birds did not react differently to deprivation of access to dustbathing material, and in general non-feather pecking birds appeared to be more fearful than feather pecking birds. Johnsen, Pernille F., K.S. Vestergaard, E. Skadhauge, and S. Arnason. 1996. Deprivation of dustbathing behavior in feather pecking and non feather pecking birds - Effect on corticosterone and tonic immobility response. *Applied Animal Behaviour Science*: 49(3) 237-246.

The standards established by the Canadian Council on Animal Care are cited in the Request for Comments as a classification of pain and distress. That is not the case. The CCAC Categories of Invasiveness are descriptive of pain levels resulting from invasive procedures that are assumed to result in certain levels of distress, but the term distress is not defined. The word distress seems to be used nearly synonymously with the word pain. The same is true of the scale proposed by the Humane Society of the United States. It fails to define distress. Instead, it simply shifts the level at which reporting would be required.

Some organizations are apparently suggesting that if APHIS determines that stress must be defined, it should be based upon currently accepted professional standards such as the definition provided by the National Research Council in its 1992 publication *Recognition and Alleviation of Pain and Distress in Laboratory Animals*. We have reviewed the definition of distress (at p.4) and find that it is lacking the quantifiable element that would resolve the subjectivity problem. For instance, it cites as possible indicia of distress abnormal feeding, absence or diminution of postprandial grooming, inappropriate social interaction with conspecifics, and inefficient reproduction. These phenomena all result from even brief episodes of handling, with little or no manipulations. Further, the definition does not recognize that these conditions may be temporary and abate or disappear over time. We also note that the NRC (at pp.2-3) itself qualifies its definition in the introduction:

There is a lack of agreement on the meaning of such terms as *comfort, well-being, discomfort, stress, fear, anxiety, pain, and distress*. The terms and classification of syndromes presented here can be used provisionally and refined as additional information and understanding become available. The definitions that follow are presented as aids to the recognition of pain, environmental stressors, and the responses they produce. They should help to form the basis for the selection of appropriate pharmacologic and nonpharmacologic approaches to the prevention and alleviation of acute stress and distress. This document assumes that an animal's state can vary across a continuum from comfort through discomfort to distress, as evidenced by the appearance of physiologic changes and maladaptive behaviors. The state of an animal depends on the nature of the stressors, the degree of stress induced, and the animal's ability to respond in such a way as to maintain or return to a state of comfort.

#### Responsibility of scientists

Both APHIS and the National Institutes of Health Office of Laboratory Animal Welfare have

long espoused a principle of scientific self-regulation. They have repeatedly resisted overseeing or regulating the Institutional Animal Care and Use Committees (IACUCs), citing this principle. We suggest that application of that principle is particularly appropriate in this case. The IACUCs are uniquely suited to assess the effect of research methodology on the animals used by the researchers in their institutions. The IACUC members are responsible for laboratory inspection and for reviewing research protocols. They are able to consider the differences among species and the necessity for the use of specific techniques.

The IACUCs themselves apparently see no need for a definition of the term “distress.” Only 76 out of 1674 Institutional Animal Care and Use Committees responded to the *three* letters from the Humane Society of the United States inviting them to join in the HSUS initiative to “eliminate unnecessary pain and distress in laboratory animals” and only 22% of those 76 elected to join with HSUS suggests that the research community itself sees no need for this effort [HSUS Fourth Letter to IACUCS, dated 23 July 1999, [http://hsus.org/programs/research/iacuc\\_letter4.html](http://hsus.org/programs/research/iacuc_letter4.html)].

### Conclusion

There is no reason to believe that a definition of the term “distress” will serve the purposes of the AWA. Unless and until there is substantial reason to believe that it will improve the care of research animals, APHIS should refrain from engaging in this extremely problematic effort. If APHIS persists in this effort, we request that the definitions expressly exclude research conducted on wild animals in their natural environments.

Sincerely,

Ellen Paul  
Executive Director