October 23, 2008

Dr. Chester Gipson
Deputy Administrator
Animal Care Unit
USDA - APHIS
4700 River Road
Suite 2D 04, Unit 97
Riverdale, MD 20737

Dear Dr. Gipson:

I am writing on behalf of The Humane Society of the United States (HSUS) and our 10 million members and constituents to share a recent proposal drafted by the Animal Procedures Committee of the Home Office and the Laboratory Animal Science Association in the United Kingdom regarding categorization of animal pain and distress. I am providing this information because this effort in the UK is pertinent to lingering pain and distress efforts by the USDA in the US. We again urge the USDA to take definitive action on its proposal entitled "Animal Welfare: Definitions for and Reporting of Pain and Distress" (*Federal Register*, July 10, 2000).

New Method for Recording Animal Suffering in the United Kingdom
On October 1, 2008, the Animal Procedures Committee of the Home Office and the Laboratory Animal Science Association in the UK proposed retrospective reporting of animal pain and distress using a retrospective categorization system based on the level of pain and/or distress (mild, moderate or substantial) that each animal actually experiences. (See attached: *Final report of a LASA/APC Working Group to examine the feasibility of reporting data on the severity of scientific procedures on animals*). This reporting system would be an overhaul of the current prospective reporting system in the UK for which researchers specify the expected level of animal suffering in advance. Under this new system, the number of animals experiencing each level of suffering will be known. When speaking of this proposal, David Smith, chairman of the committee, said "[i]t will enable scientists to be more publicly accountable and open about their work, and it could also bring animal welfare and scientific benefit."

Pain and distress categorization system: consensus within the animal research community
In July 2005, The HSUS wrote to the USDA providing the results of an analysis we conducted that shows that nearly nine out of every ten comments submitted by the research community to USDA (88.7% of over 2,000 comments) were supportive of a revised and/or changed categorization system. This demonstrates that there is general consensus among the research community and that a revised categorization system should be proposed.

According to the *Federal Register* notice itself (enclosed), "[a] different categorization system could produce data that more accurately depicts the nature of animal pain or distress and provide a better tool to measure efforts made to minimize animal pain and distress at research facilities." This statement, as well as the fact that the proposal was published, clearly indicates that the USDA recognizes the importance of improving the categorization system.

Proposed categorization system
As we have conveyed in the past, we urge the USDA to transform its current classification system into a graded scale of pain and distress that reflects levels of severity, using the categories, minor (subdivided into two categories regarding whether or not pain and/or distress relief were provided), moderate, and severe. Any "gray" areas between minor and moderate, and between moderate and severe, could be minimized through USDA guidance and exemplars (as suggested in the enclosed UK Working Group proposal).

A revised system that reflects levels of pain and distress would finally provide an accurate picture of what the research animals are experiencing and would enable stakeholders to identify and focus on those techniques that cause the most severe pain and distress. Moreover, the new system would allow international comparisons regarding animal use, given the prevalence of similarly graded severity scales overseas. This is particularly relevant as there have been major discussions related to international harmonization of efforts regarding animal research in recent months and years.

Definition of distress: recent events

Since the proposal of 2000, The HSUS has also urged USDA to define the term *distress*. In the past, the USDA has cited the lack of a definition of distress as the reason not to pursue a definition. Since that time, however, further research has been done, the results of which should allow the USDA to move forward on its proposal.

In February 2004, The HSUS convened an international expert working group on distress. The workshop participants recommended that "…an adequate definition of distress could be addressed by crafting a general description of what might constitute 'animal distress' that is supported by a set of specific examples that provide information about procedures, procedural endpoints, or situations that might be expected to produce different types and levels of distress." The Executive Summary of this workshop was published in the September 2006 issue of *Lab Animal* (enclosed).

In April 2008, the National Research Council published "Recognition and Alleviation of Distress in Laboratory Animals", which reiterates the definition of distress published in the 1992 National Research Council publication, which was largely supported by the research community in their comments to the USDA. The HSUS requests that the USDA consider adopting this definition, along with supporting examples as recommended by the expert working group convened in 2004.

Conclusion

In summary, we urge the USDA to promptly revise and simplify its categorization system so that it reflects the levels of pain and distress that animals experience in biomedical research, testing and education, as well as provide a description and supporting examples of the term "distress." It has been over eight years since the USDA published the pain and distress proposal and this issue should not be postponed any longer. Thank you for your time and consideration and we look forward to hearing your response on this matter

Sincerely,

Kathleen Conlee
Director of Program Management
Animal Research Issues

Cc: Cindy Smith, Administrator, APHIS