THE AMERICAN ASSOCIATION OF IMMUNOLOGISTS

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Response of the American Association of Immunologists (AAI) to the USDA Request for Information: Identifying and Reducing Regulatory Burdens
(https://www.federalregister.gov/articles/2015/03/17/2015-05742/identifying-and-reducing-regulatory-burdens)

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The American Association of Immunologists (AAI), the largest professional association of immunologists in the world, representing more than 7,600 basic and clinical immunologists, appreciates this opportunity to submit comments to the United States Department of Agriculture (USDA) "Request for Information (RFI): Identifying and Reducing Regulatory Burden." AAI is pleased that the USDA has initiated this effort, since regulatory burden is a significant barrier to the productivity and efficiency of the nation's scientific researchers.

In their research, AAI members use and depend on animals and therefore have a deep interest in all matters governing their care and use. AAI appreciates that the USDA is seeking ways to ensure the humane care and use of animals without unnecessarily or inadvertently reducing scientific research capacity or disrupting, impeding, or burdening the research scientists who spend their careers in search of answers and cures.

AAI members are funded by a wide range of federal agencies, including the National Institutes of Health (NIH); the Department of Defense (DOD); the Department of Veterans Affairs (VA); the USDA; the Department of Energy (DOE); and the National Science Foundation (NSF). Many members receive grants from multiple agencies over the course of their careers. As a result, AAI hopes that issues identified and addressed by USDA will spur action by, and coordination among, the many federal science agencies to reduce investigators' regulatory burdens.

In addition to our comments below, AAI urges the USDA to consider carefully the thoughtful and comprehensive comments submitted by the Federation of American Societies for Experimental Biology (FASEB), of which AAI is a founding member, and the American Physiological Society (APS). Both groups have offered well-reasoned suggestions for the reduction of regulatory burden.

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- *Exempt some biomedical procedures performed on agricultural animals from compliance with USDA regulations*

The guidelines contained in *Licensing and Registration Under the Animal Welfare Act* (AWA), *Guidelines for Dealers, Exhibitors, Transporters, and Researchers*, which were issued by the USDA's Animal and Plant Health Inspection Service (APHIS), specify that, "[i]nstitutions using any regulated live animals for research, testing, teaching, or experimentation must register with the USDA as 'research facilities'." Under the guidelines, however, "Agricultural Research Institutions" are exempt. These institutions include those that, "…perform work involving food, fiber, or agriculture and that use horses and domestic farm animals, including rabbits…" as long as they are not performing "nonagricultural biomedical research." At institutions that perform both agricultural research and nonagricultural biomedical research, the regulations require that different animals be used for agricultural research than are used for nonagricultural biomedical research, and that these groups be kept separate from each other. As a result, many institutions are forced to house and use many more animals than necessary, increasing paperwork and regulatory burden for researchers while also undermining institutional efforts to comply with the "3R's" (reduce, refine and replace). For example, blood draws are routinely used by veterinarians to assess the health of agricultural animals; these procedures do not require registration under the AWA. However, if any of that blood is used for "biomedical" purposes (e.g., sequencing or measurement of factors for experimental diagnostic purposes), then that animal would no longer be categorized as agricultural. [Examples of other AWA-prohibited activities include utilizing samples obtained from 1) agricultural animals that require more than one surgery, or 2) naturally occurring stillborn or naturally aborted fetuses.]

The AWA regulations, therefore, can increase regulatory burden and undermine efforts to reduce both the number of animals and the number of procedures that could cause pain or distress. Therefore, the USDA should exempt from AWA registration certain nonagricultural biomedical research procedures that occur in an agricultural research setting.

- *Reduce inspections from semi-annually to annually*

In section 2.31 (c) of the AWA regulations, Institutional Animal Care and Use Committees (IACUCs) are instructed to, "[r]eview, at least once every six months," the research facility's program for humane care and use of animals and animal facilities, and to submit reports to the "Institutional Office" of the research facility. IACUCs dedicate a significant amount of time to these activities. Reducing the number of reviews and reports required per year from two to one would decrease the burden on the committee without reducing the health or safety of research animals.