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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 2

[Docket No. APHIS-2015-0033]

Petition to Amend the Reporting Requirements for Research Facilities under the Animal Welfare Act Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of petition.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service (APHIS) has received a petition requesting that we amend the regulations to require that research facilities include information about the uses of animals in the annual report they submit to APHIS. We are making this petition available to the public and soliciting comments regarding any issues raised by the petition that we should consider.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0033>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0033, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The petition and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0033> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Carol Clarke, Research Program Manager, USDA, APHIS, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737-1234; (301) 851-3724.

SUPPLEMENTARY INFORMATION:

The Animal Welfare Act (AWA, 7 U.S.C. 2131 et seq.) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing research facilities. The Secretary has delegated the responsibility for enforcing the AWA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). Within APHIS, the responsibility for administering the AWA has been delegated to the Deputy Administrator for Animal Care.

Regulations and standards promulgated under the AWA are contained in title 9 of the Code of Federal Regulations, parts 1, 2, and 3 (referred to collectively below as the AWA regulations). Part 1 contains definitions of terms used within parts 2 and 3. Part 2 contains licensing and registration regulations, regulations specific to research facilities, and regulations governing veterinary care, animal identification, recordkeeping, access for inspection,

confiscation of animals, and handling, among other requirements. Within part 2, subpart C contains the regulations specific to research facilities.

The regulations in paragraph (a) of § 2.36 require that the reporting facility be the segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility is required to submit an annual report¹ to the Animal Care Regional Director for the State where the facility is located on or before December 1 of each calendar year. The annual report has to be signed and certified by the chief executive officer or institutional official and cover the previous Federal fiscal year.

Under § 2.36, the annual report is required to assure that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, were used prior to, during, and following actual procedures, and that each principal investigator has considered alternatives to painful procedures. The annual report is also required to assure that the facility is adhering to the standards and regulations under the AWA. Exceptions to the standards and regulations are required to be attached to the annual report as a summary that includes a brief explanation as well as the species and number of animals affected.

¹ Annual reports for the years they were issued can be viewed at:
http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare!/ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOK9_D2MDJ0MjDzd3V2dDDz93HwCzL29jAyCzYAKIvEo8DYITr-zu6OHibmPgYGBiYWRgaeLk4eLuaWvgYGnGXH6DXAARwNC-sP1o_AqAfkArACfE8EK8LihIDc0NMIg0xMAwhVB1g!/?1dmy&urile=wcm%3apath%3a%2FAPHIS_Content_Library%2FSA_Our_Focus%2FSA_Animal_Welfare%2FSA_Obtain_Research_Facility_Annual_Report%2F.

In addition, the regulations require the annual report to state the location of all facilities where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes.

The regulations also require the annual report to include the common names and numbers of animals involved in procedures for which: 1) No pain, distress, or use of pain-relieving drugs was involved; 2) appropriate anesthetic, analgesic, or tranquilizing drugs were provided where there was accompanying pain or distress to the animals; or 3) pain and distress was involved and the use of appropriate anesthetic, analgesic, or tranquilizing drugs for relief would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used is required to be attached to the annual report.

Lastly, the annual report is required under the regulations to include the common names and numbers of animals being bred, conditioned, or held for use in teaching, testing, research, experiments, or surgery, but not yet used for such purposes.

APHIS received a petition from the National Anti-Vivisection Society (referred to below as NAVS) dated December 15, 2014. In the petition, NAVS stated that the online Animal Care Information System² and the APHIS annual report provide an insufficient level of detail about animals used for research. NAVS requested that we amend the AWA reporting regulations to require research facilities to provide us with information about how animals are being used for research and experimentation and that we publish this information in the annual report of

² Animal Care Information System (ACIS), accessible at: <https://acisearch.aphis.usda.gov/LPASearch/faces/Warning.jspx>.

research facilities. NAVS also requested that APHIS replace the current reporting form³ used by research facilities with a template⁴ comparable to that used by Member States of the European Union (EU), which provides an accounting of the numbers and types of animals, and for what specific research, testing, and educational purposes the animals are being used.

We are making this petition available to the public and soliciting comments to help determine what action, if any, to take in response to this request. The petition and any comments submitted are available for review as indicated under ADDRESSES above. We welcome all comments on the issues outlined in the petition. In particular, we invite responses to the following questions:

1. Should APHIS amend the regulations to require research facilities that use animals for teaching, testing, and experimentation to provide specific information about how regulated animals are used (for example, for safety testing, teaching purposes, or disease research)? Would reporting this information improve animal welfare? If so, how?
2. If research facilities were required to report the purposes of their animal research activities, what types of information should be provided, and why?
3. What might be the effects, if any, on research facilities if they are required to collect and report this additional information?
4. Does the annual reporting form currently required to be used by research facilities capture sufficient information? If not, what information is missing?

³ Form 7023, Annual Report of Research Facility:
http://www.aphis.usda.gov/library/forms/pdf/APHIS_7023.pdf.

⁴The EU reporting template cited by NAVS can be viewed at http://www.navs.org/file/APHIS-Modified-Template_121214.xls.

We encourage the submission of scientific data, studies, or research to support your comments and position. We also invite data on the costs and benefits associated with any recommendations. We will consider all comments we receive.

Authority: 7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7.

Done in Washington, DC, this 18th day of June 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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