Proposed Rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 2, 3, and 4

[Docket No. APHIS–2019–0001]

RIN 0579–AE54

AWA Research Facility Registration Updates, Reviews, and Reports

AGENCY: Animal and Plant Health Inspection Service, Agriculture Department (USDA).

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Animal Welfare Act (AWA) regulations governing research facilities by removing duplicative and unnecessary information requirements. We would remove the requirement that registered research facilities update their registration information every 3 years. We also propose to remove the requirement for continual, but not less than annual, review of research animal use activities and replace it with a requirement for a complete review at least every 3 years, and to no longer require that research facilities request an inactive status if they no longer use, handle, or transport AWA covered animals. In addition, we propose to clarify the duration of a registration and conditions for its cancellation, and to no longer require that the Institutional Animal Care and Use Committee (IACUC) approve any continuing research activities involving animals, thus removing duplicative and unnecessarily duplicative regulations and policies associated with research using laboratory animals, and to look for ways to reduce administrative burden and simplify the regulations. NIH, USDA, and FDA formed a Working Group to collaborate on these tasks. Group members researched and analyzed current regulations and policies, held listening sessions with stakeholders and organizations, and issued a Request for Information. After analyzing the research data and the comments received, the Working Group issued a report recommending ways to

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covered animals. Part 4 addresses rules of practice governing proceedings under the AWA.

Within 9 CFR part 2, § 2.30 includes specific registration requirements for research facilities, including provisions for updating and changing a registration status. Section 2.31 lists membership criteria, requirements, and functions of the Institutional Animal Care and Use Committee (IACUC), which is appointed by the Chief Executive Officer of the research facility and entrusted with assessing the research facility’s animal program, facilities, and procedures. IACUC requirements include conducting continual reviews of research activities involving animals, but not less than annually. Section 2.36(a) contains requirements for submitting annual reports to APHIS.

Title II, Section 203(d) of the 2016 21st Century Cures Act (21CCA) directed the National Institutes of Health (NIH), in collaboration with the Food and Drug Administration (FDA) and the USDA, to review regulations and policies for the care and use of laboratory animals and revise them appropriately to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animals.

Among its directives, the 21CCA tasked these Agencies to identify inconsistent, overlapping, and unnecessarily duplicative regulations and policies associated with research using laboratory animals, and to look for ways to reduce administrative burden and simplify the regulations. NIH, USDA, and FDA formed a Working Group to collaborate on these tasks. Group members researched and analyzed current regulations and policies, held listening sessions with stakeholders and organizations, and issued a Request for Information. After analyzing the research data and the comments received, the Working Group issued a report recommending ways to

reduce the regulatory burden associated with research activities involving laboratory animals in several areas, including registration of research facilities, institutional reporting, and reviews of research activities that use animals. This proposed rule addresses the recommendations specific to the USDA AWA regulations.

Proposed Changes to the AWA Regulations

APHIS is proposing several changes to 9 CFR part 2 to address the reforms called for in the 21CCA and in Executive Order 13777, “Enforcing the Regulatory Reform Agenda,” 4 which tasks Federal agencies to review regulations and consider modifying, streamlining, or repealing those that are unnecessary or that impose administrative burdens or excessive costs on regulated entities. The changes we propose, detailed below, would remove or reduce registration, reporting, and review requirements of activities involving animals on research facilities registered under the AWA.

Registration of Research Facilities

Section 2.30(a)(1) currently requires that each research facility other than a Federal research facility register with the Secretary by completing and filing a registration form with the Animal Care (AC) Regional Director 5 for the State in which the research facility has its principal place of business. A facility’s registration must be updated every 3 years by completing and filing a registration update form provided by the AC Regional Director. The registration form includes fields for the registrant’s name, address, and contact information; USDA registration certificate numbers in which the registrant has an interest; names of partners, officers, and the institutional official; and a checklist for the types of animals used at the facility. USDA instituted the requirement to update the registration every 3 years to account for considerable turnover of research facility executive personnel and changes to research activities. The Department also established a procedure whereby a registrant can be placed in an inactive status after a period of 2 years during which no animals have been used, handled, or transported, and established a procedure by which a registrant which ceases to operate as a research facility, carrier, intermediate handler, or exhibitor, or which goes out of business, can request in writing to have its registration canceled.

We propose to amend § 2.30(a)(1) to eliminate the requirement to update the research facility registration every 3 years. We have determined that this requirement is burdensome and unnecessarily duplicative because, under § 2.30(c), facilities are already required to notify APHIS of any change in the name, address, or ownership, or other change in operations affecting its status as a research facility, within 10 days after making such change. Research facilities may use APHIS Form 7033-Notification of Change to provide this information.

Section 2.30(c)(2) provides that a research facility that has not used, handled, or transported animals for a period of at least 2 years, and that wishes to be placed in an inactive status, must make a written request to the AC Regional Director and file an annual report of its status (active or inactive). Each fiscal year, a small number of research facilities become inactive or are otherwise no longer subject to submitting an annual report of animal use information. We have reviewed the AWA regulations applicable to such research facilities that no longer use, handle, or transport animals covered under the Act, and determined that the requirement in § 2.30(c)(2) pertaining to requesting an inactive status and filing of an annual report constitutes an unnecessary and excessive burden to these facilities. For this reason, we propose to remove this requirement.

Facilities would no longer be in active or inactive status, but instead would either be registered or unregistered. This change would reduce administrative burden associated with animal facilities that no longer use, handle, or transport animals having to request inactive status or submit an annual report of animal use. Under proposed § 2.30(d), detailed below, an inactive research facility would have its registration canceled. In order to resume operation or otherwise conduct regulated activities in the future, such a facility would need to submit a form to reregister at least 10 days prior to using, handling, or transporting animals.

Paragraph (c)(1) of § 2.30, which requires research facilities to notify APHIS of any change in the name, address, or ownership, or other changes in operations affecting its status as a research facility within 10 days after making any such change, would remain as redesignated paragraph (c). We would modify the paragraph to inform research facilities that they may use APHIS Form 7033-Notification of Change to provide the information.

Section 2.30(c)(3) includes provisions for a research facility to cancel its registration when going out of business, ceasing to function as a research facility, or changing its method of operation so that it no longer uses or plans to use, handle, or transport animals. We would move these provisions to a new paragraph (d) in § 2.30.

Duration of Registration and Conditions for Cancellation of a Registration

We would redesignate paragraph (d) in current § 2.30 as paragraph (e) and add a new paragraph (d) that clarifies the duration of a research facility’s registration and conditions for its cancellation.

In paragraph (d)(1), we would retain the current provision that a registration will be canceled if a research facility voluntarily requests cancellation, in writing, to the Deputy Administrator.

We would also retain the provision that a registration will be canceled if the research facility notifies the Deputy Administrator that it has gone out of business, ceases to function as a research facility, or has changed its method of operation so that it no longer uses, handles, or transports animals, and does not plan to use, handle, or transport animals at any time in the future.

Additionally, we propose to add a provision in paragraph (d)(2) that the Deputy Administrator may initiate cancellation of a research facility’s registration if there is reason to believe that it has ceased to function as a research facility. Before making a decision to cancel a facility’s registration on these grounds, the Deputy Administrator would consider evidence of business inactivity, which could include but not be limited to multiple unsuccessful attempts to contact the facility by phone or mail, or no activity at the physical address listed in the registration. Therefore, we propose that the Deputy Administrator may cancel a registration if sufficient evidence exists that a facility has changed its method of operation so that it no longer uses, handles, or transports animals, and does not plan to use, handle, or transport animals at any time in the future, or that otherwise no longer meets the definition of research facility in § 1.1.
We would include in proposed paragraph (d)(3) the provision that if a research facility registration has been canceled but the research facility wishes to resume operations or otherwise conduct regulated activities in the future, the facility is responsible for submitting an application to reregister at least 10 days prior to it using, handling, or transporting animals. There would be no fees associated with such reregistration.

**IACUC Review of Activities Involving Animals**

Section 2.31 lists the functions, requirements, and committee membership criteria for the IACUC. Each research facility is required to establish an IACUC, the functions of which include reviewing and reporting on the facility’s animal program, facilities, procedures, and activities involving animals.

Section 2.31(d) requires the IACUC to conduct reviews of activities involving the care and use of research animals and to determine whether the activities are in accordance with the AWA regulations. Under the process detailed in §2.31(d), the IACUC conducts reviews of these activities and notifies the principal investigators and the research facility in writing of its decision to approve or withhold approval of activities related to the care and use of animals, or of modifications required to secure IACUC approval. Paragraph (d)(5) in §2.31 requires the IACUC of each research facility to conduct continuing reviews of such activities covered under subchapter A, Animal Welfare, at appropriate intervals as determined by the IACUC, but not less than annually.

We propose to amend §2.31(d)(5) to remove the requirement for the IACUC continuing reviews of activities covered by subchapter A, but not less than annually, and replace it with the requirement for the IACUC to conduct a complete review of approved activities at appropriate intervals as determined by the IACUC, but not less than every 3 years.

The continuing reviews served the purpose to monitor animal care and use activities to ensure they are performed as approved by the IACUC. Changes sometimes occur during the life cycle of an approved activity, such as but not limited to personnel, species, study objectives, and frequency of sample collections. The proposed complete review is intended to thoroughly examine the current and proposed animal care and use activities. The principal investigator would provide the IACUC with a written description of all current and proposed activities that involve the care and use of animals for review and approval at the end of the 3- or less-year term. This proposed change to a complete review does not affect the IACUC’s authority to conduct such monitoring when deemed necessary, as described in §2.31. The intended goal of this change is to reduce administrative burdens on investigators, IACUC members, attending veterinarians, and other related facility staff who conduct research activities involving animals. The change would result in an activity involving animals remaining approved for the interval approved by the IACUC, not to exceed 3 years, after the IACUC’s complete review, unless the IACUC suspends the activity pursuant to §2.31(d)(6). Finally, the change harmonizes with the NIH requirement for a complete review of IACUC-approved activities at 3-year intervals for federally funded research under NIH oversight and reduces burden by establishing a consistent review cycle of the activities involving animals for all AWA-registered research facilities.

**Annual Report**

The regulations in §2.36(a) contain requirements for submitting annual reports to APHIS. Each reporting facility—i.e., that 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—is required to submit an annual report to the AC Regional Director for the State where the facility is located on or before December 1 of each calendar year. The annual report must be signed and certified by the Chief Executive Officer (CEO) or Institutional Official (IO) and cover the previous Federal fiscal year.

We propose to amend §2.36(a) to eliminate the requirement for CEO and IO signatures on the paper version of the annual report. This guards against identity theft through written signatures. It also allows for the facility representative to electronically submit the annual report on behalf of the CEO or IO while maintaining the assurance requirements regarding the content of the annual report and practices at the research facility. A separate signed hard copy of the annual report would not be required. We would also modify §2.36(a) to inform registered research facilities and Federal research facilities that APHIS Form 7023A, 7023B, and 7023C are forms which may be used by registered research facilities and Federal research facilities to submit the information required by §2.36(b).

**Miscellaneous**

In parts 2, 3, and 4 of the current regulations, we propose to make minor corrections in punctuation and wording to improve readability. In §2.38, we propose to amend paragraph (g)(1) by correcting punctuation. In paragraphs (f)(6) and (7) of §3.111, we propose to remove extraneous punctuation and wording. In §§4.10 and 4.11, we propose to add pronouns that are more inclusive.

**Executive Orders 12866, 13563, and 13771 and Regulatory Flexibility Act**

This proposed rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget. This proposed rule is not an Executive Order 13771 regulatory action because it is not significant under Executive Order 12866. Further,APHIS considers this rule to be a deregulatory action under Executive Order 13771 as the proposed actions are intended to reduce duplicative and unnecessary administrative burden on AWA-registered research facilities while ensuring the integrity and credibility of research findings and protection of research animals.

In accordance with 5 U.S.C. 603, we have performed an initial regulatory flexibility analysis, which is summarized below, regarding the economic effects of this proposed rule on small entities. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov website (see ADDRESSES above for instructions for accessing Regulations.gov).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

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6 Public Health Service policy requires “continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with IV.C–4 at least once every three years.” Available at https://olaw.nih.gov/policies-laws/phs-policy.htm.
Section 2034(d) of the 21st Century Cures Act, “Reducing Administrative Burden for Researchers: Animal Care and Use in Research,” directed the Director of National Institutes of Health, the Secretary of Agriculture, and the Commissioner of Food and Drugs to reduce administrative burden on investigators by identifying and reducing inconsistent, overlapping, or duplicative regulations and policies while ensuring the integrity and credibility of research findings and protection of research animals.

Accordingly, APHIS is proposing changes to §§ 2.30, 2.31, and 2.36 of the Animal Welfare regulations:

Registration
- Section 2.30(a)(1): Eliminate the requirement for research facility registration updates at 3-year intervals;
- Section 2.30(c): Eliminate the requirement for a research facility to request being placed on inactive status if the facility has not used, handled, or transported animals for a period of at least 2 years;
- Section 2.30(d): Clarify the duration of a registration and conditions for cancellation of a registration:

IACUC
- Section 2.31(d)(5): Replace continuing annual reviews of activities involving animals approved by the IACUC with reviews and approval by the IACUC at intervals not exceeding 3 years; and

Annual Report
- Section 2.36(a): Eliminate the requirement for Chief Executive Officer and Institutional Official signatures on the reporting facility annual report.

APHIS has quantified annual savings for facilities that totally approximately $80,000 from the proposed changes in § 2.30(a)(1) and approximately $11,000 from the proposed change in §2.36(a), respectively. APHIS also expects that the proposed changes in § 2.30(c)(2) and (3) would reduce administrative burden of certain inactive research facilities. APHIS conservatively estimates that the proposed change in § 2.31(d)(5) would be cost neutral as no quantifiable information is available to show expected net cost savings from the change.

These proposed changes are intended to reduce administrative burden on investigators, IACUC members, attending veterinarians, and other related facility staff, and would not affect the Animal Welfare regulations that ensure humane animal care during research, testing, experiments, or teaching. Facilities covered by this proposed rule include small entities. APHIS requests that the public provide any information that may strengthen this analysis of expected economic effects.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. The Act provides administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The information collection activities in this proposed rule are included under the Office of Management and Budget (OMB) control number 0579–0036, which has been submitted to OMB for approval.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the EGovernment Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mr. Joseph Moxey, APHIS’ Information Collection Specialist, at (301) 851–2483.

List of Subjects

9 CFR Part 2
Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

9 CFR Part 3
Animal welfare, Marine mammals, Pets, Reporting and recordkeeping requirements, Research, Transportation.

9 CFR Part 4
Administrative practice and procedure, Animal welfare.

Accordingly, we propose to amend 9 CFR parts 2, 3, and 4 as follows:
without a written request from the research facility.

(3) If a research facility resumes operation or otherwise wishes to conduct regulated activities in the future, the facility is responsible for submitting a form to reregister at least 10 days prior to it using, handling, or transporting animals. There are no fees associated with such reregistration.

(e) Non-interference with APHIS officials. * * *

3. In § 2.31, paragraph (d)(5) is revised to read as follows:

§ 2.31 Institutional Animal Care and Use Committee (IACUC).

* * * * *

(d) * * *

(5) The IACUC shall conduct complete reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than every 3 years. The IACUC shall provide a written description of all proposed activities that involve the care and use of animals for review and approval at the end of the term;

* * * * *

4. In § 2.36, paragraph (a) is revised to read as follows:

§ 2.36 Annual report.

(a) The reporting facility shall be that 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 shall submit an annual report to the Deputy Administrator on or before December 1 of each calendar year. The report shall cover the previous Federal fiscal year. The Annual Report of Research Facility (APHIS Form 7023), Continuation Sheet for Annual Report of Research Facility (APHIS Form 7023A), and Annual Report of Research Facility Column E Explanation (APHIS Form 7023B) are forms which may be used to submit the information required by paragraph (b) of this section.

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§ 3.111 [Amended]

7. Section 3.111 is amended in paragraphs (f)(6) and (7) by removing “, which”.

PART 4—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE ANIMAL WELFARE ACT

8. The authority citation for part 4 continues to read as follows:

Authority: 7 U.S.C. 2149 and 2151; 7 CFR 2.22, 2.80, and 371.7.

§ 4.10 [Amended]

9. In § 4.10, paragraph (a) is amended by removing the words “he” and “his” and adding the words “he or she” and “his or her” in their places, respectively.

§ 4.11 [Amended]

10. In § 4.11, paragraph (a) introductory text is amended by removing the word “his” and adding the words “his or her” in its place.

Done in Washington, DC, this 9th day of September 2020.

Mark Davidson,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–20512 Filed 9–16–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION
Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0818; Project Identifier MCAI–2020–00987–A]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Pilatus Aircraft Ltd. (Pilatus) Model PC–24 airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI identifies the unsafe condition as electrical harness installations on PC–24 airplanes that are not in compliance with the approved design. This unsafe condition could lead to wire chafing and potential arcing or failure of wires having the incorrect length, possibly resulting in loss of system redundancy, or generation of smoke and smell, or loss of power plant fire protection function. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by November 2, 2020.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

• Federal eRulemaking Portal: Go to https://www.regulations.gov. Follow the instructions for submitting comments.

• Fax: 202–493–2251.

• Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12 140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

• For service information identified in this NPRM, contact Pilatus Aircraft Ltd., CH–6371, Stans, Switzerland; telephone: +41 848 24 7 365; email: techsupport.ch@pilatus-aircraft.com; internet: https://www.pilatus-aircraft.com/. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call 816–329–4148. It is also available on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0818.

Examining the AD Docket

You may examine the AD docket on the internet at https://www.regulations.gov by searching for and locating Docket No. FAA–2020–0818; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the MCAI, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:
Doug Rudolph, Aerospace Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: doug.rudolph@faa.gov.

SUPPLEMENTARY INFORMATION: