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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 Official or Chief Executive Officer sign the annual report. We would also make miscellaneous changes to improve readability. The changes we propose would reduce duplicative requirements and administrative burden on research facilities, maintain research integrity and oversight, and ensure that research animals continue to receive humane care.

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-2019-0001>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2019-0001, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2019-0001> or in our reading room, which is located in room 1620 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. Kay Carter-Corker, Director, National Policy Staff, Animal Care, APHIS, 4700 River Road Suite 6D-03E, Riverdale, MD 20737; (301) 851-3748; [kay.a.carter-corker@usda.gov](mailto:kay.a.carter-corker@usda.gov).

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Welfare Act (AWA or the Act, 7 U.S.C. 2131 *et seq.*), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, exhibitors, operators of auction sales, research facilities, and carriers and intermediate handlers. The

Secretary has delegated responsibility for administering the AWA to the Administrator of the U.S. Department of Agriculture's (USDA's) 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. Definitions, regulations, and standards established under the AWA are contained in 9 CFR parts 1, 2, and 3 (referred to below as the regulations). Part 1 contains definitions for terms used in parts 2 and 3. Part 2 provides administrative regulations and sets forth institutional responsibilities for regulated parties. Part 3 provides standards for the humane handling, care, treatment, and transportation of 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 2034(d) of the 2016 21st Century Cures Act (21CCA)<sup>1</sup> 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.

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<sup>1</sup> <https://www.congress.gov/bill/114th-congress/house-bill/34/>.

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.<sup>2</sup> After analyzing the research data and the comments received, the Working Group issued a report<sup>3</sup> 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,”<sup>4</sup> 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,

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<sup>2</sup> NIH, Office of Laboratory Animal Welfare, “Request for Information: Animal Care and Use in Research,” March 2018 (NOT-OD-18-152). Available at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-152.html>.

<sup>3</sup> NIH, FDA, and USDA, “Reducing Administrative Burden for Researchers: Animal Care and Use in Research,” August 2019. Available at [https://olaw.nih.gov/sites/default/files/21CCA\\_final\\_report.pdf](https://olaw.nih.gov/sites/default/files/21CCA_final_report.pdf).

<sup>4</sup> Published in the *Federal Register* on March 1, 2017. Available at <https://www.federalregister.gov/documents/2017/03/01/2017-04107/enforcing-the-regulatory-reform-agenda>.

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<sup>5</sup> 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

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<sup>5</sup> As part of a program reorganization, the AC Regional Director position has been retired. Duties and responsibilities formerly under the purview of the AC Regional Directors are now under the Deputy Administrator in all 50 States. In a final rule published May 13, 2020 (85 FR 28772-28799; Docket No. APHIS-2017-0062) and effective November 9, 2020, we amended the regulations in part 2 to remove the term "AC Regional Director" and replace it with "Deputy Administrator."

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<sup>6</sup> 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 7023, 7023A, and 7023B are forms which may be used by registered research facilities and Federal research facilities to submit the information required by § 2.36(b).

### Miscellaneous

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<sup>6</sup> 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>.

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.

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 total 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 E-Government 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:

PART 2—REGULATIONS

1. The authority citation for part 2 continues to read as follows:

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

2. Section 2.30 is amended as follows:

- a. By revising paragraphs (a)(1) and (c);
- b. By redesignating paragraph (d) as paragraph (e);
- c. By adding a new paragraph (d); and
- d. By adding a heading for newly redesignated paragraph (e).

The revisions and additions read as follows:

§ 2.30 Registration.

(a) \* \* \*

(1) Each research facility, other than a Federal research facility, shall register with the Secretary by completing and filing a properly executed form which will be furnished, upon request, by the Deputy Administrator. The registration form shall be filed with the Deputy Administrator. Except as provided in paragraph (a)(2) of this section, where a school or department of a university or college uses or intends to use live animals for research, tests, experiments, or teaching, the university or college rather than the school or department will be considered the research facility and will be required to register with the Secretary. An official who has the legal authority to bind the parent organization shall sign the registration form.

\* \* \* \* \*

(c) *Notification of change of operation.* A research facility shall notify the Deputy Administrator by certified mail 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. The Notification of Change form (APHIS Form 7033) may be used to provide the information.

(d) *Duration of a registration and conditions for cancellation of a registration.* (1) A research facility that goes out of business or ceases to function as a research facility, or that changes 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, may have its registration canceled by making a written request to the Deputy Administrator.

(2) If the Deputy Administrator has reason to believe that a research facility has ceased to function as a research facility, then the Deputy Administrator may cancel the registration on its own, 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 be provided 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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§ 2.38 [Amended]

5. In § 2.38, paragraph (g)(1) introductory text is amended by removing the period after the word “acquired” and adding a comma in its place.

PART 3—STANDARDS

6. The authority citation for part 3 continues to read as follows:

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

§ 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.