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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 2

[Docket No. APHIS-2020-0101]

RIN 0579-AC69

Handling of Animals; Contingency Plans

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Animal and Plant Health Inspection Service issued a final rule on December 31, 2012, to establish regulations under which research facilities and dealers, exhibitors, intermediate handlers, and carriers must meet certain requirements for contingency planning and training of personnel. Implementation of the final rule was stayed on July 31, 2013, so that the agency could conduct additional review to further consider the impact of contingency plan requirements on regulated entities. Since that time, we have conducted such a review, and the 2021 Congressional Appropriations Act has required us to propose to lift the stay. We are therefore proposing to lift the stay and make minor revisions to the requirements in order to update compliance dates and clarify intent. The lifting of the stay and proposed revisions would better ensure that entities responsible for animals regulated under the Animal Welfare Act are prepared to safeguard the health and welfare of such animals in the event of possible emergencies or disasters.

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 www.regulations.gov. Enter APHIS-2020-0101 in the Search field.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0101, 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 www.regulations.gov 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. Elizabeth Theodorson, DVM, MPH, Assistant Deputy Administrator, Animal Care, APHIS, 4700 River Road Unit 86, Riverdale, MD 20737; (970) 494-7473.

SUPPLEMENTARY INFORMATION:

Background

Under the Animal Welfare Act (AWA) (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, research facilities, exhibitors, carriers, and intermediate handlers. The Secretary has

delegated authority 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 APHIS' Animal Care program (AC). Regulations and standards established under the AWA are contained in 9 CFR parts 1, 2, and 3 (referred to below as the regulations).

Following the events experienced during the 2005 hurricane season, AC concluded that entities responsible for animals covered by the AWA could better safeguard the health and welfare of their animals by developing contingency plans for possible emergencies or disasters (situations which could reasonably be anticipated and expected to be detrimental to the good health and well-being of the animals in the regulated entity's possession). Consequently, on December 31, 2012, APHIS published in the *Federal Register* (77 FR 76815-76824, Docket No. APHIS-2006-0159) a final rule¹ establishing regulations under which research facilities and dealers, exhibitors, intermediate handlers, and carriers of animals regulated under the AWA must meet certain requirements for developing contingency plans and training personnel in their role and responsibilities related to the contingency plan.

After learning that a number of small entities considered the requirements of these regulations excessive for their specific cases, and determining there to be validity to such a claim, on July 31, 2013, we published in the *Federal Register* (78 FR 46255, Docket

¹ To view the final rule, go to <https://www.regulations.gov/document/APHIS-2006-0159-0209>.

No. APHIS-2006-0159) a stay² of the regulations to reexamine any unique circumstances and costs that may vary by the type and size of businesses affected by the final rule.

Since that time, APHIS has issued *de minimis* exemptions to animal licensure. On June 4, 2018, we published in the *Federal Register* (83 FR 25549-25555, Docket No. APHIS-2014-0059) a final rule³ that exempted from licensing dealers with four or fewer breeding female pet animals, small exotic or small wild mammals (such as hedgehogs, degus, spiny mice, prairie dogs, flying squirrels, jerboas, domesticated ferrets, chinchillas, and gerbils), and/or domesticated farm-type animals (such as cows, goats, pigs, sheep, llamas, and alpacas), and added an exemption from licensing for exhibitors who maintained eight or fewer pet animals, small exotic or small wild mammals, and/or domesticated farm-type animals for exhibition.

Following issuance of the 2018 final rule, APHIS notified 525 licensees operating small businesses that they may be newly eligible for exemption from requirements under the amended regulations. As of December 2020, 259 licensees have canceled their licenses, and we anticipate that this number will increase on a rolling basis as licenses meet their expiration dates. APHIS believes that these broadened exemptions address the concerns that led to the stay, and that contingency planning requirements remain an important safeguard for the health and welfare of animals regulated under the AWA.

Additionally, on December 27, 2020, the 2021 Congressional Appropriations Act (Pub. L. 116-260) required APHIS to propose to lift the stay on the final rule establishing

² To view the stay of the regulations, go to <https://www.regulations.gov/document/APHIS-2006-0159-0214>.

³ To view the final rule, go to <https://www.regulations.gov/document/APHIS-2014-0059-0032>.

requirements for contingency plans within 180 days of issuance of that Act. Consistent with our own evaluation, as well as the terms of the Act, we are issuing this proposed rule to lift the stay.

We are also proposing to make minor changes to the contingency plan regulations. These changes include updating the compliance dates by which regulated entities must create their contingency plans to 180 days after the effective date of a final rule following this proposed rule; modifying the dates regarding when regulated entities must provide training to personnel to 60 days after the contingency plan being put in place; removing an extraneous reference to additional requirements for marine mammals to minimize confusion; and removing the requirement that facilities as well as dealers, exhibitors, intermediate handlers, and carriers document their personnel's participation in requisite trainings.

Finally, to increase the ease of and decrease the time burden associated with contingency planning, AC has created an optional form that entities may use to develop and document a contingency plan. The form would be available on the APHIS AC website, in the USDA Forms library on the USDA website, or upon request by email to animalcare@usda.gov or by mail to USDA/APHIS/AC, 2150 Centre Ave., Building B, Mailstop 3W11, Fort Collins, CO 80526-8117. We are proposing to add a reference to this form in the regulations.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management

and Budget. Details on the estimated costs of this proposed rule can be found in the rule's economic analysis.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. 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 impact 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 kinds of small entities that may incur benefits or costs from the implementation of this proposed rule.

While it is difficult to quantify the benefits of contingency planning, they are numerous. First, contingency planning can prevent loss of animal life and any resulting undisposed carcasses that pose a threat to public health. Second, loss of valuable research resources and income can be mitigated with contingency planning. Third, having a contingency plan can reduce the time of recovery from disasters and thus provide cost savings to the affected businesses and organizations and allow for business continuity. Finally, required contingency planning will reassure the general public that facilities have measures in place to ensure the welfare of the animals in times of catastrophic and common emergencies.

APHIS' AC program will be providing a fillable form that can be used to develop and document the contingency plan; however, entities that have contingency plans in place may use those. For example, we believe that Public Health Service-funded research facilities and Association of Zoos and Aquariums zoos and aquariums have already developed contingency plans; they would not need to adopt the template. The template is intended to aid entities currently without a written contingency plan, and we estimate it will take 1-2 hours per entity to complete the plan, which includes the time to collect and document the required information. We anticipate that the use of this form will improve compliance and expedite the time for annual review by regulated entities of the plan. APHIS also estimates it will take up to 1 hour to train employees on the operations of the plan, which consists of familiarizing employees with their roles and responsibilities as outlined in the plan. APHIS invites comments on the time it may take to develop and implement contingency plans for the proposed rule and to provide the employee training required by the proposed rule. The Agency invites suggestions for

guidance or other information that would help regulated facilities achieve compliance at minimum costs.

We estimated lower and upper range estimates of costs for licensees and registrants to develop contingency plans in the first year. As noted above, we assume an average of 1 to 2 hours is required to prepare and implement a contingency plan using the form and 1 hour for employee training in the first year. We multiplied this time by the average industry-specific wage rate of the entities. Our estimate of the total one-time cost to develop the contingency plans across all affected entity categories ranges from about \$185,000 to about \$370,000 and \$185,000 for employee training, as well as possible capital costs, which will differ from entity to entity and which we accordingly are not able to estimate in aggregate. These estimates may be high, given our inclusion of entities that may currently have comparable contingency plans and already provide employee training, but for which we lack verifying information. We request specific public comment on our estimates.

The 1 to 2 hours that we assume would be required to develop a contingency plan includes the time needed to identify resources for the plan's preparation and documentation. The 1-hour training estimate for all current and new employees considers the time it would take an employee to become familiar with their roles and responsibilities as outlined in the plan. The costs included in this analysis reflect training for the first year only. Contingency planning also requires recordkeeping, ensuring that the contingency plans are kept current, and employee training. The type of training and type of contingency plan required may differ depending on the type of organization or business, as well as its location and the location's climate history.

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 does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with contingency planning, we have prepared an environmental assessment. The environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the Regulations.gov website or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading ADDRESSES at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, “Consultation and Coordination with Indian Tribal Governments.” Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

Based on the foregoing, the USDA’s Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian Tribes and determined that consultation is not required at this time. If consultation is requested, OTR will work with APHIS to ensure quality consultation is provided.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Written comments and recommendations for the proposed information collection should be sent within 60 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. Please send a copy of your comments to: (1) Docket No. APHIS-2020-0101, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road

Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, Room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

The proposed rule would amend the current regulations and would require all licensees and registrants, which include research facilities, dealers, exhibitors, intermediate handlers, and carriers, to develop, document, and maintain contingency plans for the handling of animals during all emergencies or disasters.

We are soliciting comments from the public (as well as affected agencies) concerning the new proposed optional APHIS form for creating and documenting them, as well as our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public burden for this collection of information is estimated to average 1.75 hours per response.

Respondents: Dealers, exhibitors, research facilities, carriers, and intermediate handlers.

Estimated annual number of respondents: 8,795.

Estimated annual number of responses per respondent: 2.

Estimated annual number of responses: 17,590.

Estimated total annual burden on respondents: 30,783 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

A copy of the information collection may be viewed on the Regulations.gov website or in our reading room. (A link to Regulations.gov and information on the location and hours of the reading room are provided under the heading ADDRESSES at the beginning of this proposed rule.) A copy may also be obtained from Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851-2483. APHIS will respond to any ICR-related comments in the final rule. All comments will also become a matter of public record.

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' Paperwork Reduction Act Coordinator, at (301) 851-2483.

List of Subjects in 9 CFR Part 2

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

Accordingly, we propose to amend 9 CFR part 2 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. Amend § 2.38:

a. By lifting the stay on paragraph (1);

b. In paragraph (1)(2):

i. In the first sentence by removing the date “July 29, 2013” and adding “[DATE 180 DAYS AFTER EFFECTIVE DATE OF FINAL RULE]” in its place;

ii. In the next to last sentence by removing the words “and training records”; and

ii. By revising the last sentence; and

c. By revising paragraph (1)(3).

The revisions read as follows:

§ 2.38 Miscellaneous.

* * * * *

(1) * * *

(2) * * * The APHIS Contingency Plan form may be used to keep and maintain the information required by paragraph (1)(1) of this section and this paragraph (1)(2).

(3) The facility must provide training for its personnel regarding their roles and responsibilities as outlined in the plan. For current registrants, training of facility personnel must be completed within 60 days of the research facility putting their plan in place; for research facilities registered after [DATE 180 DAYS AFTER EFFECTIVE DATE OF FINAL RULE] training of facility personnel must be completed within 60 days of the facility putting its contingency plan in place. To fulfill this training requirement, employees hired 30 days or more before the contingency plan is put in place must be trained by the date the facility puts its contingency plan in place. For employees hired less than 30 days before that date or after that date, training must be conducted within 30 days of their start date. Any changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

3. Amend § 2.134:

a. By lifting the stay on the section;

b. In paragraph (b):

i. In the first sentence by removing the date “July 29, 2013” and adding “[DATE 180 DAYS AFTER EFFECTIVE DATE OF FINAL RULE]” in its place;

ii. In the fifth sentence by removing the words “and training records”; and

iii. By revising the last sentence; and

c. By revising paragraph (c).

The revisions read as follows:

§ 2.134 Contingency planning.

* * * * *

(b) * * * The APHIS Contingency Plan form may be used to keep and maintain the information required by § 2.38(l)(1) and (2).

(c) Dealers, exhibitors, intermediate handlers, and carriers must provide training for their personnel regarding their roles and responsibilities as outlined in the plan. For current licensees and registrants, training of dealer, exhibitor, intermediate handler, and carrier personnel must be completed within 60 days of the licensee and registrant putting their contingency plan in place; for new dealers, exhibitors, intermediate handlers, or carriers licensed or registered after [DATE 180 DAYS AFTER EFFECTIVE DATE OF FINAL RULE], training of personnel must be completed within 60 days of the dealer, exhibitor, intermediate handler, or carrier putting their contingency plan in place. To fulfill this requirement, employees hired 30 days or more before the contingency plan is put in place must be trained by the date the licensee or registrant puts their contingency plan in place. For employees hired less than 30 days before that date or after that date, training must be conducted within 30 days of their start date. Any changes to the plan as a result of the annual review must be communicated to employees through training which must be conducted within 30 days of making the changes.

Done in Washington, DC, this 16th day of June 2021.

Mae Wu,

Deputy Under Secretary for Marketing and Regulatory Programs.

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