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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 2 and 3

[Docket No. APHIS-2006-0159]

RIN 0579-AC69

Handling of Animals; Contingency Plans

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the Animal Welfare Act regulations to add requirements for contingency planning and training of personnel by research facilities and by dealers, exhibitors, intermediate handlers, and carriers. We are taking this action because we believe all licensees and registrants should develop a contingency plan for all animals regulated under the Animal Welfare Act in an effort to better prepare for potential disasters. This action will heighten the awareness of licensees and registrants regarding their responsibilities and help ensure a timely and appropriate response should an emergency or disaster occur.

EFFECTIVE DATE: January 28, 2013.

FOR FURTHER INFORMATION CONTACT: Dr. Jeanie Lin, Eastern Region Emergency Programs Manager, Animal Care, APHIS, 920 Main Campus Drive, Raleigh NC 27606; (919) 855-7100.

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. Regulations established under the AWA are contained in the Code of Federal Regulations (CFR) in 9 CFR parts 1 and 2, and 9 CFR part 3 contains standards for the humane handling, care, treatment, and transportation of animals covered by the AWA. Currently, part 3 consists of subparts A through E, which contain specific standards for dogs and cats, guinea pigs and hamsters, rabbits, nonhuman primates, and marine mammals, respectively, and subpart F, which sets forth general standards for warmblooded animals not otherwise specified.

The only requirement for contingency planning by licensees and registrants in the regulations has been in § 3.101(b), which covers water and power supply requirements at facilities housing marine mammals. Specifically, this section requires such facilities to submit written contingency plans to the Deputy Administrator of Animal Care (AC) regarding emergency sources of water and electric power should primary sources fail. Among other things, the plans must include evacuation plans in the event of a disaster and a description of backup systems and/or arrangements for relocating marine mammals requiring artificially cooled or heated water.

Following the events experienced during the 2005 hurricane season, a Federal document, "The Federal Response to Katrina: Lessons Learned," which can be found on the Internet at http://georgewbush-whitehouse.archives.gov/reports/katrina-lessons-learned/, was published that

highlighted the need for planning to minimize the impact of disasters. AC's experience indicates that, although contingency planning would benefit the health and welfare of animals covered by the AWA, at least some entities responsible for regulated animals have not undertaken such planning. We believe all licensees and registrants should be required to develop a contingency plan for all animals regulated under the AWA in an effort to better prepare for potential disasters. Therefore, on October 23, 2008, we published in the Federal Register (73 FR 63085-63090, Docket No. APHIS-2006-0159) a proposal[1] to amend the AWA regulations to add requirements for contingency planning and training of personnel by research facilities and by dealers, exhibitors, intermediate handlers, and carriers.

We solicited comments concerning our proposal for 60 days ending on December 22, 2008. On December 19, 2008, we published a notice in the Federal Register (73 FR 77554) that extended the comment period an additional 60 days until February 20, 2009. We received 997 comments by that date. They were from private citizens, breeders, dealers, animal welfare organizations, research facilities, Government agencies, pharmaceutical companies, universities and colleges, research associations, exhibitors, carriers, kennels, and medical associations. Fifty commenters supported the rule as it was proposed. The issues raised by the remaining commenters are discussed below by topic.

Many commenters had comments or questions that were not germane to the proposed rule, such as asking the Animal and Plant Health Inspection Service (APHIS) to end the trade of exotic animals. We are not addressing those comments in this final rule because they are outside of its scope.

[1] To view the proposed rule and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2006-0159.

Objections to Mandating Contingency Plans

Many commenters objected to APHIS mandating contingency plans. One commenter stated that, since no plan can be 100 percent successful, it does not make sense to mandate plans. One commenter stated that the AWA has language prohibiting prescribing methods of research and that the proposed rule violates this by prescribing emergency planning methods.

As stated in the proposed rule, the events experienced during the 2005 hurricane season highlighted the need for planning to minimize the impact of disasters on the health and welfare of all animals covered by the AWA. The intent of the proposed rule was to safeguard the health and welfare of animals in emergency situations. We understand that contingency plans may not be 100 percent successful. However, we do not agree that plans should not be mandated because, to promote animal welfare, entities should be able to demonstrate a reasonable effort to address emergency situations. The rule does not prescribe emergency planning methods. In addition, we do not consider a contingency plan to be a research method.

One commenter suggested that instead of mandated plans, APHIS should provide guidance materials, training videos, or classes, as it would be cheaper for both APHIS and the regulated entities.

APHIS plans to provide guidance materials, which may include videos and classes. However, this does not replace a need for contingency plans as contingency plans are more adaptable to the unique circumstances of each licensee and registrant and will determine what training is needed. In addition, as facilities have widely varying needs, allowing licensees and registrants to determine and implement their own unique training allows flexibility and will potentially keep training costs down. We have prepared guidance materials that are being made

available concurrently with this final rule on our Web site[2] and will provide additional guidance to licensees and registrants for drafting appropriate contingency plans upon request.

Several commenters stated that they already had contingency plans in place or followed other accreditation standards (e.g., Association of Zoos and Aquariums standards), which they stated were sufficient to address the contingency plan components we proposed to require. Some of these commenters asked that they be exempt from the requirements of the rule because they already had plans in place or that APHIS work with other organizations that have accreditation standards to draft a standard document so that the regulations are not redundant. One commenter stated that APHIS should have done a better job of talking to facilities that already have contingency plans in place.

We recognize that many AWA licensees and registrants may already have contingency plans in place. Although many of these plans may be sufficient to satisfy the new contingency plan requirements in this final rule, exemption is not practical as those nongovernmental accreditation standards are not mandatory, nor are they linked by regulatory processes to the AWA. However, before developing the proposed rule, we gathered information on regulated entities that currently have contingency plans in place. This information was used as a basis for the proposed criteria for developing contingency plans.

Submission of Contingency Plans

Many commenters asked how APHIS will review the contingency plans, and in particular whether we will require submission of contingency plans to APHIS. Many commenters objected to submitting contingency plans because they were concerned that the plans would be subject to the Freedom of Information Act (FOIA) and that disclosure of contingency plans would put at risk the safety and security of facilities, employees, and animals by giving animal rights

[2] http://www.aphis.usda.gov/animal_welfare/awa_contingency_plan.shtml.

extremists important information. Many other commenters supported submitting contingency plans to APHIS or other agencies or making them available to the public or making relevant portions of plans available to local services identified by facilities as potentially important to the execution of their contingency plan. One commenter suggested posting contingency plans online while another suggested electronic submission. Several commenters stated that licenses should be revoked or not renewed if contingency plans are not submitted to APHIS or that plans that have been modified due to personnel changes or updates should be submitted to APHIS.

We do not intend to require submission of contingency plans. As stated in the analysis of significant alternatives to the rule in the proposed rule, there are over 10,000 licensees and registrants and requiring each of them to submit plans to APHIS for review would take an enormous amount of resources for the Agency to process, review, and store. Therefore, we proposed that each research facility, dealer, exhibitor, intermediate handler, or carrier will be required to review their contingency plan on at least an annual basis. We would expect that each licensee and registrant would maintain documentation of their annual reviews, including documenting any amendments or changes made to their plan since the previous year's review, such as changes made as a result of recently predicted, but historically unforeseen, circumstances (e.g., weather extremes). We are making this clarification in § 2.38(l)(2) and § 2.134(b). We are also clarifying that APHIS will have the opportunity to review annual review documentation and training records, as well as contingency plans, as a part of our routine inspection process. It is the regulated facility's decision whether or not to share its plan with outside entities. The AWA does not require licensees and registrants to disclose documentation to outside entities. However, if a contingency plan details coordination with other government entities, an inspector may check for evidence supporting this coordination.

Expertise

Several commenters stated that there is no evidence that APHIS has more expertise in contingency planning than other organizations, such as universities. One commenter stated that APHIS should consult with other agencies such as the Federal Emergency Management Agency (FEMA) in the development of requirements for contingency plans or in the implementation of contingency plans.

APHIS already has the technical expertise to ensure that regulated entities protect the health and well-being of animals in accordance with the AWA. Further, in 2008, APHIS launched an Animal Care Emergency Programs unit, which is a full-time unit dedicated to collaborating with other organizations to support the safety and well-being of animals during emergencies and disasters. As required by the AWA, APHIS consults and cooperates with other Federal agencies concerned with the welfare of animals used for research, experimentation, or exhibition. APHIS also routinely works closely with FEMA and other organizations on animal welfare issues prior to and during disasters and emergencies.

Several commenters stated that the facility and not the Government should decide what should be in contingency plans.

As stated in the proposed rule, because we recognize that individual circumstances for regulated entities may be different, it is difficult to go into specific detail as to what elements must be included in all contingency plans. Therefore, we have not sought to develop a one-size-fits-all plan but have instead provided a framework of four criteria, in § 2.38(l)(1) for research facilities and § 2.134 for dealers, exhibitors, intermediate handlers, and carriers, that we believe are the minimum criteria necessary to ensure a successful contingency plan. We have largely left to the discretion of each regulated entity how best to develop contingency plans that:

- Identify common emergencies such as electrical outages, faulty HVAC systems, fires, animal escapes, and natural disasters the facility is most likely to experience.
- Outline specific tasks required to be carried out in response to the identified emergencies including, but not limited to, specific animal evacuation plans or shelter-in-place plans and provisions for providing backup sources of food and water as well as sanitation, ventilation, bedding, veterinary care, etc.
- Identify a chain of command and who (by name or by position title) will be responsible for fulfilling these tasks.
- Address how response and recovery will be handled in terms of materials, resources, and training needed.

We believe that fulfilling these criteria is essential to the success of a contingency plan. In addition, we believe that these criteria provide an adequate degree of flexibility to allow all regulated entities to comply with the provisions of this final rule. These criteria are essential because they form a framework of what potential events to address, who has responsibility, and how to mitigate the potential events. These criteria form the basis of FEMA's "Ready Business" campaign, which provides information to businesses on how to plan for emergencies. We have modified that information to address animal welfare concerns.

Specific Criteria

One commenter stated that the contingency plan should identify and evaluate the location of the facility and the probable specific emergency situations that location is likely to experience. The commenter further stated that any facility-specific vulnerability should be identified and addressed. One commenter stated that facility grounds should be in areas not prone to flooding or earthquakes and that it is preferable to provide onsite care during an emergency.

One of the proposed criteria for development of contingency plans is that the plan identify situations, such as emergencies and natural disasters, that a regulated entity is most likely to experience that would trigger the need for the measures identified in a contingency plan to be put into action. We expect that, if a facility-specific vulnerability would impact the humane handling and care of AWA-regulated animals during an emergency, the vulnerability would be addressed within the regulated entity's contingency plan. While we agree that ideally a regulated entity would not be located in an area prone to flooding or earthquakes, we realize that is not always feasible to ensure. As stated in the proposed rule, such disasters, if likely to be encountered by a particular regulated entity, would be expected to be addressed in that regulated entity's contingency plan.

Several commenters stated that euthanasia should be considered a viable option in the event of a disaster. Several commenters stated that marine mammals should be microchipped to facilitate recovery in the event they are released into the wild. One commenter stated that all tasks necessary for ensuring the welfare of animals should be itemized and the time required for each task estimated. Several commenters recommended providing criteria for development of contingency plans by animal group or by species and, for marine mammals, criteria by geographic location. Several commenters stated that agreements with alternative facilities for evacuation should be part of the contingency plan.

Since each regulated entity has different needs, we have largely left to the discretion of each regulated entity how best to fulfill the criteria of this final rule. Details about elements to include in a contingency plan, such as whether to use microchip identification methods or euthanasia or whether to itemize and time tasks, are to be decided upon by the regulated entity. In addition, as long as a regulated entity addresses each of the elements required for contingency

plans, it may divide its plan according to criteria such as animal group, species, or geographic location. While we encourage regulated entities to explore cost-efficient options such as entering into mutual aid agreements with nearby similar entities, we are not requiring them to do so, as long as their contingency plans are adequate to protect the animals' welfare.

As noted previously, the only contingency planning currently required for licensees and registrants are those requirements in § 3.101(b) which cover water and power supply requirements for facilities housing marine mammals. One commenter suggested that the requirements in § 3.101(b) be revised to require that contingency plans submitted for marine mammals include the proposed criteria for contingency plans included in § 2.134.

The regulations added in this final rule in § 2.134 for developing contingency plans apply to all dealers, exhibitors, intermediate handlers, and carriers, including those that handle marine mammals. We are amending § 3.101(b) in this final rule to make it clear that facilities housing marine mammals must comply with the contingency planning requirements in § 2.134.

Transportation

Several commenters stated that carriers and intermediate handlers should not have to develop contingency plans because it would be costly for them, because the number of animals lost or harmed in transit is miniscule, or because they have limited resources to respond to emergency situations. Given this, several commenters expressed concern that, if forced to comply with the proposed rule, carriers may not want to do business with research facilities.

We believe that all research facilities, dealers, exhibitors, intermediate handlers, and carriers should be required to develop a contingency plan for all animals regulated under the AWA. Although there may be costs associated with developing contingency plans, we expect such costs to be reasonable given that we have largely left it up to the discretion of regulated

entities to determine the best way to fulfill the contingency plan criteria provided in this final rule for their own unique circumstances (i.e., size, type of entity, location, etc.). Therefore, we do not expect that developing contingency plans will cause a significant financial burden on carriers and intermediate handlers. At a minimum, we would expect that carriers, intermediate handlers, and traveling exhibitors would have provisions in place to respond to weather-related problems and animal escapes, as well as other problems, such as mechanical failures, most likely to be experienced during transit. We do not necessarily expect carriers and intermediate handlers to have backup sources of food and water on hand when traveling, but we would expect that their contingency plan would document how and where to get them if needed. In addition, we are clarifying in § 2.134(b) that all traveling entities must carry a copy of their contingency plan with them at all times and make it available for inspection while in travel status. Having a copy of their contingency plan on hand will allow regulated entities to refer directly to their plan in the event of an emergency while traveling. We believe this will result in preventing the loss or harm of regulated animals.

Several commenters stated that facilities should have backup carriers if their plans require evacuation. Also, the commenters stated that carriers should include in their plans which facility to service first in the event that a major disaster happens and multiple facilities are impacted.

While we do not require regulated entities to employ backup carriers, if a regulated entity's contingency plan includes a backup carrier, we expect that the regulated entity will ensure that the carrier is compliant with the elements of the contingency plan. In addition, we believe that carriers should coordinate with the facilities they serve.

Because we realize that some dealers, exhibitors, intermediate handlers, and carriers do not have stationary facilities, we are making a change to the requirements in § 2.134(a)(1) by

removing the word “facility” and replacing it with the more inclusive words “licensees and registrants.” In addition, we are adding “mechanical breakdowns” to the list of likely emergencies that may be addressed in a contingency plan.

Several commenters stated that licensees who travel with animals should be required to submit contingency plans both for at home and on the road. Several commenters stated that travel as part of contingency plans for dangerous animals or for marine mammals should be prohibited unless necessary for the welfare of the animals because of the risks to public safety and animal welfare, particularly in emergency situations. One commenter asked how animals that cannot be evacuated will be cared for and stated that there needs to be a requirement for securing a facility in the event animals cannot be evacuated. One commenter stated that the contingency plan must document how and by whom animals would be moved and what efforts will be made to ensure the relocation of animals is done in the most humane or least stressful manner possible.

The intent of the proposed rule was to safeguard the welfare of animals in emergency situations. There is no requirement to travel with animals unless it is part of a facility’s contingency plan. As stated in the proposed rule, the contingency plan would have to provide detailed instructions for evacuation or shelter-in-place. Therefore, if a contingency plan includes provisions for evacuation, we expect that the plan will also include details on how and by whom the animals would be moved in a way that would be as humane as possible given the disaster circumstances a facility may be facing.

One commenter asked whether an outside carrier's equipment, if called upon, would have to comply with AWA requirements.

Regulated entities are expected to ensure that their routine and back-up carriers are compliant with all AWA requirements.

Disasters

Several commenters stated that detailed evacuation or shelter-in-place plans may be possible for emergencies, but are impractical for natural disasters because regulated entities rarely have advance notice of disasters and because there are so many variations in facilities and disasters that it does not make sense to have a one-size-fits-all plan. The commenters further stated that the rule should acknowledge this and allow for a "best efforts" approach when making contingency plans for unpredictable natural disasters. Several commenters expressed concern that the proposal seemed to require that all potential disasters be addressed no matter how likely they are to occur. However, one commenter stated that all potential disasters that might occur should be addressed in the contingency plan.

We recognize that it is not practical to prescribe detailed contingency plans for all situations. Therefore, we have not sought to develop a one-size-fits-all plan, but have largely left to the discretion of each regulated entity how best to fulfill the criteria described in the proposed rule. This rule intends to set the minimum criteria necessary to ensure a successful contingency plan. We believe this provides an adequate degree of flexibility to allow all regulated entities to comply with the provisions of the rule. As stated in the proposal, we would require that regulated entities address those emergencies and disasters most likely to occur, rather than requiring them to address all possible disasters and emergencies regardless of likelihood. We encourage regulated entities to consider all scales of emergencies, but recognize that highly localized events such as power disruptions and road closures (e.g., from a vehicular accident) are most likely. APHIS encourages the regulated communities to address these more routine events

in their contingency plans, and to work with their local emergency management organization. APHIS understands that disaster and emergency events may be unpredictable and that it is impossible for every possible event to be addressed in a contingency plan.

One commenter stated that the contingency planning requirements are inconsistent with Homeland Security Presidential Directive 8: National Preparedness (HSPD-8) because terms used in the rule, such as "major disaster" and "emergency," are not consistent with those used in the directive.

HSPD-8 establishes policy for dealing with terrorist attacks, major disasters, and other events of national scope. Section 2(e) of the directive states that the terms "major disaster" and "emergency" are defined in section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act. Under that Act, “emergency” is defined as any occasion or instance, as determined by the President, where Federal assistance is needed to save lives, protect property and public health and safety, or to lessen or avert a catastrophe. A “major disaster” is defined as any natural catastrophe, as determined by the President, which causes damage of sufficient severity and magnitude to warrant major disaster assistance in order to supplement the efforts and available resources of States, local governments, and disaster relief organizations in alleviating the damage, loss, hardship, or suffering caused by the catastrophe. The Stafford Act is largely a framework for Federal assistance to State and local governments for disaster relief, and these terms require Presidential involvement. The scope of this rule is broader, and thus we use the terms "disaster" and "emergency" in more general terms. This rule considers “disaster” and “emergency” to mean those events which disrupt the ability of a licensee or registrant to continue with normal business routine and which are expected to be detrimental to the good health and well-being of the animals in the licensee’s or registrant’s care. A core concept of

emergency management is that emergencies are managed at the most local level possible. The National Incident Management System, December 2008, supports this in stating that “incidents typically begin and end locally, and are managed on a daily basis at the lowest possible geographical, organizational, and jurisdictional level.” The document is available from the FEMA Web site at http://www.fema.gov/pdf/emergency/nims/NIMS_core.pdf. While emergencies and disasters may be Statewide or even national in scope, we expect that most often they will be events that do not generally involve disaster declarations and that remain localized, such as power outages, facility fires, or ice storms.

One commenter stated that contingency plans should be integrated into the overall hazard response plan for facilities.

Although we do not require regulated entities to integrate animal contingency plans into their business continuity plans, we encourage them to do so. APHIS believes that having a business continuity plan supports animal health and welfare as well as overall good business practices.

Backups

The proposed requirements in §§ 2.38(l)(1)(ii) and 2.134(a)(2) stated that regulated entities must include in their contingency plans provisions for providing backup sources of food and water as well as sanitation, ventilation, bedding, veterinary care, etc. Several commenters recommended that we remove the words "backup sources of" from this provision and insert the words "as described in the contingency plan" after the phrase "as well as sanitation, ventilation, bedding, veterinary care, etc." These commenters stated that it may not be possible to maintain all of the veterinary care provisions listed in § 2.33(b) during a disaster.

While it may not be possible to provide the same level of veterinary care during an emergency or disaster as during normal business operations, APHIS believes that the veterinary care requirements in § 2.33(b) are the minimum requirements necessary to ensure the health and welfare of regulated animals. As with the contingency plan criteria, these veterinary care requirements are general rather than specific to allow regulated entities the discretion to determine how best to fulfill the requirements based on their own unique situations. In addition, as backup veterinary care is an element that must be addressed within the contingency plan, APHIS will be able to assess the adequacy of the backup veterinary care as it assesses the adequacy of veterinary care overall during routine inspections.

Review and Enforcement

Several commenters expressed concern regarding APHIS' ability to provide adequate inspection and review of plans, stating that the review of plans would present an excessive burden to APHIS. One commenter suggested that APHIS could reduce the inspection burden by reviewing a random sampling of plans. Two commenters suggested that, at a minimum, APHIS should review the contingency plans of facilities with dangerous animals such as elephants, nonhuman primates, or large carnivores. One commenter asked who APHIS would pay to obtain the extra staff to enforce the rule. One commenter suggested that licensing fees be increased to fund additional inspectors or that APHIS stop issuing licenses until numbers of facilities drop to a manageable level.

We do not believe that our review of contingency plans would present an excessive burden on APHIS. As noted above, we would review contingency plans as a part of the routine inspection process, similar to the process for our review of dog exercise and nonhuman primate environment enhancement plans. We believe in this way we will be able to provide adequate

review of the contingency plans for all regulated entities. We do not anticipate that additional APHIS staff will need to be hired as a result of this rule. Neither do we anticipate needing to contract out to other organizations to obtain additional staff.

Many commenters were concerned that there were not enough specifics about what would make a contingency plan acceptable and that facilities could be cited for failing to include certain items in their plans or for not following their plans exactly. Several commenters suggested punishments for facilities that either do not submit their plans or whose plans are inadequate. One commenter asked whether the judgment of noncompliance will be affected by whether animals were harmed in any way.

We have issued a guidance document along with this final rule that will assist licensees and registrants in determining what elements to include in their contingency plans. The guidance document is intended only to provide suggestions for how regulated entities may satisfy the criteria in the regulations rather than to prescribe specific measures that must be undertaken or equipment that must be purchased. For example, a regulated entity has multiple options to mitigate the potential failure of an HVAC system besides purchasing a backup generator, some of which are no-cost solutions. These no-cost solutions might include the use of a borrowed generator, opening windows, using existing fans, and/or moving the animals to a cooler location. Any of these actions could be considered adequate ways of responding to the potential failure of an HVAC system and could therefore be included in a contingency plan as long as the action listed is actually feasible. For instance, if a regulated entity's contingency plan calls for opening windows, but the facility's windows are incapable of opening, opening windows would not be a valid mitigation measure. We wish to emphasize that compliance with this final rule will be achieved through the development of an appropriate contingency plan and the training of facility

personnel with respect to that plan. Nothing in this rule should be construed as requiring affected entities to make capital expenditures – for example, purchasing backup generators or making structural changes to a facility – in order to comply with the rule. As we do currently when enforcing the regulations, APHIS will assess the adequacy of a regulated entity's contingency plan using the Animal Welfare Act and Animal Welfare Regulations. This may be demonstrated by the plan itself, training records, the presence of materials and resources mentioned in the plan, or a documented history of responses to similar situations. An adequate contingency plan is one in which the minimum criteria considered necessary for a successful contingency plan have been addressed. Enforcement action may be taken on a case-by-case basis.

One commenter asked if missing the training deadline by a few days would result in noncompliance with the training requirements in the regulations regarding the contingency plan.

All noncompliant items, including failure to train employees on the components of the contingency plan, found during inspection would be documented on the inspection report and may be subject to enforcement action on a case-by-case basis. Enforcement actions may include issuance of official warnings, civil monetary penalties, license suspension, or license revocation. Licensees and registrants are expected to comply with all requirements of the regulations and standards, including training deadlines.

Several commenters asked who would be determining the adequacy of plans and what training they would have.

APHIS inspectors will review and determine the adequacy of contingency plans. We will provide training to the inspection personnel on evaluating contingency plans pursuant to the criteria set forth in this rule.

One commenter asked on what basis regulated entities would be expected to determine what natural disasters they may face and whether and how this determination will be evaluated by inspectors.

In the proposed rule we provided links to the U.S. Geological Survey "Hazards" Web site and the Weather Channel "WeatherREADY" Web site. These Web sites are good resources for determining the natural disasters facilities are most likely to encounter in their location. We would largely leave it up to the regulated entity to determine which natural disasters they may face. However, if it is apparent the regulated entity is likely to encounter a disaster that the contingency plan does not address (e.g., a facility in Florida that has experienced hurricanes in the past), APHIS inspectors will notify the entity and give the entity time to add provisions for responding to the disaster in the contingency plan. We anticipate that inspectors, who are typically stationed in the local area surrounding the facility, will be able to provide further guidance on potential natural disasters.

One commenter stated that the rule should be revised to include language relieving a regulated facility of responsibility if a higher emergency response authority steps in.

We expect that most emergencies will be of a local nature, such as facility fires or water main breaks. For emergencies or disasters of a larger scale, APHIS will consider the roles of jurisdictional emergency response authorities with respect to contingency plan implementation. It is not the intent of the rule to interfere with local, State, or Federal jurisdictional emergency response activities.

Training

As stated in the proposed rule, training of personnel could be developed and offered by the research facility, dealer, exhibitor, intermediate handler, or carrier or provided by an outside

entity. Several commenters stated that training requirements should be identified, including how facilities will document training. One commenter stated that a checklist should be implemented with staff signing off that they have read the standard operating procedures and completed training. Two commenters stated that there should be requirements for training and availability of backup personnel or for ensuring intermediate personnel replacement and training. Several commenters stated that trial runs of the contingency plan must be carried out.

As stated previously, because we recognize that individual circumstances for regulated entities may be different, it is difficult to go into specific detail as to what elements must be included in all contingency plans. Therefore, we do not believe it appropriate to provide technical and tactical requirements, such as protocols for personnel replacement and training, in the regulations. We anticipate that inspectors may confirm that contingency plan training is delivered in a similar manner to their current process for confirming that other required training has been delivered (e.g., for husbandry practices and veterinary care protocols). Such confirmation may include reviewing training documentation maintained by the regulated entity or asking involved employees questions about facility practices. While we have not specifically mandated trial runs of contingency plans, training may include trial runs in order to prepare licensees and registrants adequately in the event of a disaster or emergency.

One commenter stated that both position title and name of employees who play a part in implementing the contingency plan should be included in the contingency plan.

As stated in the proposed rule, regulated entities would need to identify a chain of command and who (by name or position title) will be responsible for fulfilling required tasks. We would leave it up to the regulated entity whether to include both position title and name or whether to include one or the other.

Several commenters stated that training should only apply to individuals who have a role to play within the contingency plan.

We believe the decision of which individuals should be trained is a decision best left up to the discretion of the regulated entity. However, we would expect all personnel who may be involved in or impacted by an emergency or disaster to be trained at an appropriate level.

Dates

In the proposed rule, we proposed to require that contingency plans be in place 180 days after the effective date of this final rule. In addition, we proposed that training of personnel would have to take place within 60 days following the adoption of a contingency plan by the research facility, dealer, exhibitor, intermediate handler, or carrier. Employees hired within 30 days or less after adoption of the contingency plan would have to be trained in that 60-day period while employees hired more than 30 days after adoption of the contingency plan would have to be trained within 30 days of their start date.

Several commenters asked that we further push back the effective date of the regulations to allow time to finalize contingency plans. One commenter stated that it was unclear whether the adoption date mentioned in the proposed rule is the date the rule is adopted or the date plans must be in place and that, if it is the former, the rule needs to be revised since this would require training to be completed before the contingency plan, which will guide the training, is in place. The commenter further stated that the 180-day period for having plans in place should begin at the later of either the effective date of the final rule or the date of issuance of guidance documents by APHIS. Two commenters asked whether the 180-day timeframe for having contingency plans in place includes procuring all necessary materials and resources for

implementing the contingency plan. The commenters stated that if such is the case, it is too short of a timeframe to gather materials and resources that are not currently available within a facility.

As stated in the proposed rule, the adoption date is the date the contingency plan must be in place. For current licensees and registrants, this date is 180 days after the effective date of this final rule. For future licensees and registrants, we expect the licensee or registrant to have a contingency plan in place prior to conducting regulated activities. We are making changes to paragraphs (l)(2) and (l)(3) in § 2.38 and paragraphs (b) and (c) in § 2.134(b) in order to make it clearer that the adoption date is the date the contingency plans must be finalized. Training of personnel must take place within 60 days after the adoption date. We believe 180 days is a sufficient length of time to ensure that contingency plans are in place and to procure any necessary materials and resources for implementing contingency plans.

Several commenters stated that the 30-day training requirement for newly hired personnel is unnecessary and not in keeping with the lack of specificity for the rest of the plan.

We believe that it is important to ensure that employees of a regulated entity are familiar with the regulated entity's contingency plan. Therefore, it is appropriate to require that training occur within 30 days.

Guidance

One commenter stated that guidance documents for developing contingency plans should be developed by a lead organization with expertise in collaboration with outside organizations. One commenter stated that guidance documents should not be developed by entities outside of APHIS but that stakeholders/licensees should have input. Several commenters objected to guidance documents or other means for providing criteria outside of the regulations at all.

Several commenters stated that the guidance document should be made available via the Internet, and released with the final rule.

APHIS has expertise in collaborating with outside organizations and is also responsible for enforcing the AWA. Therefore, it is appropriate for us to take the lead role in developing guidance documents to support contingency planning. As stated previously, we are providing a guidance document with this final rule. During the comment period for the proposed rule, we asked for public comment, including comment from stakeholders and licensees, on what elements should be included in the guidance document. To reiterate, APHIS will assess the adequacy of a regulated entity's contingency plan using the Animal Welfare Act and Animal Welfare Regulations. The guidance document provides suggestions for how regulated entities may satisfy the criteria in the regulations.

One commenter said that USDA should provide guidance on how contingency plans might address elements unique to each facility. One commenter suggested that APHIS create a Web site with more information that includes guidelines, checklists, and templates. Several commenters supplied examples of contingency plans, links to contingency plans, or resources for drafting contingency plans.

We are issuing a guidance document that may assist regulated entities in addressing the circumstances unique to their location or facility. We also reviewed the information provided by the commenters and will make a list of helpful resources available on our Web site (see footnote 2). The guidance document is intended to be only a tool when considering how a facility might meet the regulatory requirements, and does not provide a new set of criteria.

Economic and Paperwork Concerns

Many commenters stated that the proposed rule will cause a serious financial impact, especially on small businesses, which make up the majority of those affected. Several commenters stated that a cost-benefit study has not been conducted and asked that APHIS withdraw the rule until one has been conducted or until APHIS has evaluated whether the rule is truly necessary.

A preliminary regulatory impact analysis was conducted for the proposed rule and a final regulatory impact analysis has been conducted for this rule. A summary of the final regulatory impact analysis appears in this document under the heading "Executive Orders 12866 and 13563 and Regulatory Flexibility Act." The full analysis may be viewed on the Regulations.gov Web site (see footnote 1) or obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT. One of the components of the preliminary regulatory impact analysis is a cost-benefit analysis. APHIS has estimated that about 5 hours, on average, will be required by a facility to develop a contingency plan, using guides provided and recommended by APHIS. Depending on the size and type of regulated entity and its circumstances, this cost, in terms of the time needed to develop a contingency plan, will vary; some facilities will require less than 5 hours to develop their plans and other entities will require more time. APHIS estimates that it will take 4 to 6 hours to develop and document a contingency plan. We note that many large regulated entities, in particular, already have contingency plans. In addition to the costs associated with the development of a contingency plan, there may also be certain expenditures necessitated by the regulated entity's plan itself. As an example, a particular regulated entity's plan may call for a backup generator to supply electricity in case of a power outage. We expect such costs to total within a reasonable range given that we have largely left it

up to the discretion of facilities to determine the best way to fulfill the contingency plan criteria provided in the proposed rule for their own unique circumstances (i.e., size, type of entity, location, etc.). The costs of developing a plan and related equipment purchases should be viewed in terms of the benefits of reduced risk of harm to the animals under a regulated entity's care when there is an emergency or disaster. A reasonably scaled contingency plan that has identified potential emergencies and natural disasters therefore contributes to a regulated entity's long-term operational strength and financial security. To the extent to which the animals held by a licensee or registrant represent a capital asset or business investment, we do not believe it is unreasonable to expect that entities will have already put in place measures to ensure the continued well-being of those animals. Thus, the actual amount of new costs incurred by regulated entities due solely to the identification of a need during the development of a contingency plan should not be significant.

One commenter stated that the rule does not comply with the Regulatory Flexibility Act because it shifts the burden of investigating what would be required for a contingency plan to businesses. One commenter expressed concern that the Small Business Administration was not consulted when developing the proposed rule.

The Regulatory Flexibility Act requires that Federal agencies endeavor to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration. APHIS recognizes that each regulated entity is the best judge of the particular measures that should be included in its contingency plan. APHIS is minimizing the burden of the rule for small entities by allowing each one to determine for

itself how best to meet the requirements in accordance with the general criteria and guidance documents. APHIS also consulted with the Small Business Administration in the preparation of the proposed rule and this final rule.

One commenter stated that since the rule is significant and an Initial Regulatory Flexibility Analysis was prepared that APHIS is required to publish a compliance guide which will help regulated industries comply with the regulation.

The guidance document that we are making available concurrently with this rule will assist licensees and registrants in complying with the regulation. Any additional compliance guides will be posted on the APHIS Web site (see footnote 2) and made available to the public to further assist small entities in complying with this rule.

Two commenters asked whether they would have to build additional alternative facilities, or, if not, what shelter would be acceptable on a temporary basis, and whether USDA is ready to help shoulder some of the costs until a facility can be repaired. One commenter expressed concern that they would need to purchase disaster insurance.

We do not intend to require the building of alternative facilities. While the costs for development and execution of the plan are expected to be borne by the regulated entity, they will be determined based on the emergencies and potential natural disasters most likely to be experienced by the regulated entity. As stated previously, we expect that these costs will be reasonable. The purpose of a contingency plan is to help ensure that licensees and registrants are able to respond in a timely and appropriate manner should an emergency or disaster occur. Disaster insurance is not required by this rule, and promoting the purchase of disaster insurance is not an objective of this rule.

Three commenters expressed concern that the number of animals lost during Hurricane Katrina as stated in the economic analysis of the proposed rule is greater than the total number of regulated animals in Louisiana.

In the preliminary regulatory impact analysis, APHIS may have inadvertently implied that the number of animals covered under the Animal Welfare Act that were harmed or killed as a result of Hurricane Katrina was comparable to the 50,000 pets that reportedly were negatively impacted by the disaster. This is incorrect. There is a difference in scale between the number of animals for which pet owners are responsible versus the number of animals for which research facilities and other licensed and registered facilities are responsible. Therefore, AWA licensees and registrants caring for large numbers of animals who did not have contingency plans in place likely found it difficult to evacuate or otherwise ensure the animals' safety during Hurricane Katrina. Our intent in the proposed rule was to illustrate this fact rather than to compare the number of regulated animals negatively impacted to the number of pets that were negatively impacted. We have reexamined the available data and we present our findings in the full final regulatory flexibility analysis, which can be viewed on the Regulations.gov Web site (see the address listed in footnote 1).

One commenter suggested that a tiered contingency plan system be implemented to accommodate small businesses.

As a practical matter, one would expect that the smaller the business, the smaller the scale of the contingency plan that the business would be expected to prepare, just as a large entity with numerous animals would require a larger scale, more complex contingency plan. Because we recognize that individual circumstances may be different between research facilities, dealers, exhibitors, carriers, and intermediate handlers, we have provided general contingency

plan criteria and largely left it up to the discretion of regulated facilities to determine how best to fulfill the criteria. Because the response to each criterion will be appropriate to the size of each individual entity, it is reasonable to describe the contingency plan system provided for by this rule as tiered.

Several commenters expressed concern regarding the costs of and time for drafting a contingency plan. One commenter stated that the rule may be imposing redundant paperwork requirements because of similar requirements at the State and local levels.

Many regulated facilities are currently required to have contingency plans by other organizations (e.g., accrediting institutions, State and local regulators). Many of these plans will meet the proposed contingency plan requirements, and paperwork redundancies for entities with such plans should be minimal. Those regulated facilities that do not already have plans in place may incur an additional burden to develop contingency plans. However, we believe that having an established contingency plan promotes animal welfare and will aid in business continuity, therefore reducing the burden on facilities and regulated animals in the event of a natural disaster or emergency.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act.

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

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 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 on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

Preparedness for emergencies and disasters can reduce the harm to animals and their loss of life. The devastating impact of the 2005 hurricane season underscores the need for contingency planning for all animals covered under the Animal Welfare Act. Currently, only facilities that house marine mammals are required under 9 CFR 3.101 to develop contingency plans. The final rule requires that all of the more than 10,000 licensees and registrants develop and document contingency plans for all other animals covered under the Act. In addition, training to carry out contingency plans will be required of a regulated entity's employees. The majority of establishments that will be affected by this rule are small, based on industry estimates obtained from the Economic Census and the Census of Agriculture.

The full final regulatory flexibility analysis identifies breeders, wholesale dealers, licensed and registered exhibitors, registered research facilities, and registered transport carriers and handlers as those entities most likely to be impacted by the requirement for the development of contingency plans. While no economic data are available on business size for the specific

entities, we may assume the majority of the potentially impacted establishments are small, based on the industry estimates obtained from the Economic Census and the Census of Agriculture.

The final rule will impose certain costs to develop and document the contingency plans and provide employee training, but these costs are not expected to be excessive. The cost of training personnel will vary depending on the type and size of business. However, many organizations offer training courses on general disaster planning specific to the type of animals at the particular facility or operation. FEMA offers free training, while some organizations offer courses with prices ranging from $50 to $300. These courses cover the development and implementation of contingency plans. In addition, many of the larger facilities, in particular, already have contingency plans in place. APHIS recognizes that each entity is the best judge of the particular measures that should be included in its contingency plan, and will provide general criteria and guidance documents to minimize compliance costs. Each entity will determine for itself how best to meet the rule's requirements.

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 7 CFR part 3015, subpart V.)

Executive Order 12988

This final 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.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579-0352.

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 rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

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.

Accordingly, we are amending 9 CFR chapter I, subchapter A, 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 2.38 is amended by adding new paragraphs (i)(4) and (l) to read as follows:

§ 2.38 Miscellaneous.

* * * * *

(i) * * *

(4) The other person or premises must either be directly included in the research facility's contingency plan required under paragraph (l) of this section or must develop its own contingency plan in accordance with paragraph (l) of this section.

* * * * *

(l) Contingency planning. (1) Research facilities must develop, document, and follow an appropriate plan to provide for the humane handling, treatment, transportation, housing, and care of their animals in the event of an emergency or disaster (one which could reasonably be anticipated and expected to be detrimental to the good health and well-being of the animals in their possession). Such contingency plans must:

(i) Identify situations the facility might experience that would trigger the need for the measures identified in a contingency plan to be put into action including, but not limited to, emergencies such as electrical outages, faulty HVAC systems, fires, and animal escapes, as well as natural disasters the facility is most likely to experience.

(ii) Outline specific tasks required to be carried out in response to the identified emergencies or disasters including, but not limited to, detailed animal evacuation instructions or shelter-in-place instructions and provisions for providing backup sources of food and water as well as sanitation, ventilation, bedding, veterinary care, etc.;

(iii) Identify a chain of command and who (by name or by position title) will be responsible for fulfilling these tasks; and

(iv) Address how response and recovery will be handled in terms of materials, resources, and training needed.

(2) For current registrants, the contingency plan must be in place by July 26, 2013. For research facilities registered after this date, the contingency plan must be in place prior to conducting regulated activities. The plan must be reviewed by the research facility on at least an annual basis to ensure that it adequately addresses the criteria listed in paragraph (l)(1) of this section. Each registrant must maintain documentation of their annual reviews, including documenting any amendments or changes made to their plan since the previous year's review, such as changes made as a result of recently predicted, but historically unforeseen, circumstances (e.g., weather extremes). Contingency plans, as well as all annual review documentation and training records, must be made available to APHIS and any funding Federal agency representatives upon request. Facilities maintaining or otherwise handling marine mammals in captivity must also comply with the requirements of § 3.101(b) of this subchapter.

(3) The facility must provide and document participation in and successful completion of training for its personnel regarding their roles and responsibilities as outlined in the plan. For current registrants, training of facility personnel must be completed by September 27, 2013 for research facilities registered after July 26, 2013, training of facility personnel must be completed within 60 days of the facility putting its contingency plan in place. Employees hired 30 days or more before the contingency plan is put in place must also be trained by that date. 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. Section 2.102 is amended by adding new paragraphs (a)(4) and (b)(3) to read as follows:

§ 2.102 Holding facility.

(a) * * *

(4) The other person or premises must either be directly included in the dealer's or exhibitor's contingency plan required under § 2.134 or must develop its own contingency plan in accordance with § 2.134.

* * * * *

(b) * * *

(3) The other person or premises must either be directly included in the intermediate handler's contingency plan required under § 2.134 or must develop its own contingency plan in accordance with § 2.134.

4. A new section § 2.134 is added to read as follows:

§ 2.134 Contingency planning.

(a) Dealers, exhibitors, intermediate handlers, and carriers must develop, document, and follow an appropriate plan to provide for the humane handling, treatment, transportation, housing, and care of their animals in the event of an emergency or disaster (one which could reasonably be anticipated and expected to be detrimental to the good health and well-being of the animals in their possession). Such contingency plans must:

(1) Identify situations the licensee or registrant might experience that would trigger the need for the measures identified in a contingency plan to be put into action including, but not limited to, emergencies such as electrical outages, faulty HVAC systems, fires, mechanical breakdowns, and animal escapes, as well as natural disasters most likely to be experienced;

(2) Outline specific tasks required to be carried out in response to the identified emergencies or disasters including, but not limited to, detailed animal evacuation instructions or shelter-in-place instructions and provisions for providing backup sources of food and water as well as sanitation, ventilation, bedding, veterinary care, etc.;

(3) Identify a chain of command and who (by name or by position title) will be responsible for fulfilling these tasks; and

(4) Address how response and recovery will be handled in terms of materials, resources, and training needed.

(b) For current licensees and registrants, the contingency plan must be in place by July 26, 2013. For new dealers, exhibitors, intermediate handlers, and carriers licensed or registered after this date, the contingency plan must be in place prior to conducting regulated activities. The plan must be reviewed by the dealer, exhibitor, intermediate handler, or carrier on at least an annual basis to ensure that it adequately addresses the criteria listed in paragraph (a) of this section. Each licensee and registrant must maintain documentation of their annual reviews, including documenting any amendments or changes made to their plan since the previous year's review, such as changes made as a result of recently predicted, but historically unforeseen, circumstances (e.g., weather extremes). Contingency plans, as well as all annual review documentation and training records, must be made available to APHIS upon request. Traveling entities must carry a copy of their contingency plan with them at all times and make it available for APHIS inspection while in travel status. Dealers, exhibitors, intermediate handlers, and carriers maintaining or otherwise handling marine mammals in captivity must also comply with the requirements of § 3.101(b) of this subchapter.

(c) Dealers, exhibitors, intermediate handlers, and carriers must provide and document participation in and successful completion of training for 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 by September 27, 2013. For new dealers, exhibitors, intermediate handlers, or carriers licensed or registered after July 26, 2013, training of personnel must be completed within 60 days of the dealer, exhibitor, intermediate handler, or carrier putting their contingency plan in place. Employees hired 30 days or more before their contingency plan is put in place must also be trained by that date. 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.

PART 3–STANDARDS

5. 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.

6. In § 3.101, paragraph (b) is amended by adding a new sentence at the end of the paragraph to read as follows:

§ 3.101 Facilities, general.

* * * * *

(b) * * * Facilities handling marine mammals must also comply with the requirements of § 2.134 of this subchapter.

* * * * *