

February 2, 2009

Cindy Smith
Administrator
Animal and Plant Health Inspection Service
1400 Independence Avenue, SW
Room 312E, Whitten Building
Washington, DC 20250

Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737

**Re: Handling of Animal; Contingency Plans, Docket No. APHIS-2006-0159
73 Fed. Reg. 63085 (October 23, 2008)**

Dear Administrator Smith:

As Acting Chief Counsel for Advocacy, I am submitting comments on this matter because I am concerned about the agency's compliance with the requirements of the Regulatory Flexibility Act (RFA)¹ in this rulemaking. Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before Federal agencies and Congress. Section 612 of the RFA also requires Advocacy to monitor agency compliance with the RFA. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

In this rulemaking the Animal and Plant Health Inspection Service (APHIS) is proposing to amend provisions of the Animal Welfare Act (Act) to add requirements for contingency planning and training of personnel by research facilities and dealers, exhibitors, intermediate handlers and carriers for all animals regulated under the Act. APHIS states in the proposed regulation that for the purposes of its RFA analysis, it assumes that the majority of the establishments that would be affected by this rule are small.² My office has received letters from small businesses that are concerned with APHIS' assumptions contained in the rule's Regulatory Impact Analysis and Initial Regulatory Flexibility Analysis (IRFA). More specifically, those small businesses

¹ 5 U.S.C. §§ 601-612.

² 73 Fed. Reg. 63087.

disagree with APHIS' conclusion that the economic impacts associated with the rule will only impose minimal costs on the affected industries.³ Further, they believe that APHIS has failed to analyze the economically burdensome nature of this regulation on small businesses pursuant to the requirements of the RFA.

Advocacy has the following comments on the proposed rule which will not undermine the important public policy goals of APHIS.

I. The RFA requires APHIS to perform a more detailed analysis of the economic impacts of the regulation.

A. Section 605(b) of the RFA provides that if the head of the agency cannot certify that the regulation will not have a significant economic impact on a substantial number of small entities, then the agency must perform an IRFA. The law states that the IRFA shall address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; a description of any reasonable alternatives; and all Federal rules that may duplicate, overlap, or conflict with the proposed rule.⁴

Advocacy appreciates that APHIS prepared an IRFA pursuant to the requirements of the RFA. As part of its analysis, APHIS admitted that it did not have data on the size of the affected industries, nor was it able to estimate the cost of implementing contingency plans for facilities that do not already have such plans in place.⁵ It appears that APHIS decided to provide the affected businesses with a general set of criteria for the contingency plan. This would essentially shift the burden of investigating what would be required to draft a compliant contingency plan to the affected businesses by noting that there is a wealth of information available from various Federal and State agencies and private organizations that address animal disaster planning.⁶ Assuming that affected entities currently have adequate information to address disaster planning is not consistent with the requirements of the RFA. The burden is on the agency to provide adequate information and analysis.⁷

Without information on the rule's economic burden, APHIS is not in compliance with section 604(a)(1-4) of the RFA, and the agency does not have a factual basis for assuming that the costs of the regulation would be minimal for the affected entities. Despite APHIS' assertion that it lacked access to the data, APHIS could have done a better job of gathering data from those industries that are already complying with the contingency plan requirements of the Act. Section 3.101(b) of the Act requires facilities that house marine mammals to submit contingency plans which contain water and power

³ *Id.*

⁴ 5 U.S.C. § 604(a)(1-4).

⁵ 73 Fed. Reg. 60387.

⁶ *Id.*

⁷ The RFA provides that, "when adopting regulations to protect the health, safety and economic welfare of the Nation, Federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public." Pub. L. No. 96-354.

supply back-up should an emergency exist. The same section requires that the contingency plans 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.

While Advocacy appreciates that there is a marked difference between how marine mammals and the animals included in the proposed rule are handled under an emergency situation, it is reasonable for APHIS to draw some parallels between the costs associated with drafting contingency plans under section 3.101(b) of the Act and what will be required of businesses affected by the instant rulemaking. Section 3.101(b) of the Act requires that the marine facilities file their contingency plans with the Deputy Administrator of Animal Care at APHIS. APHIS can reach out to businesses contained in the contingency plan database and ask them what was involved in the drafting of their contingency plans, how much time it took, and then obtain an estimate of the cost. Advocacy is not suggesting that APHIS should have performed a formal survey of marine animal facilities that would have been subject to Paperwork Reduction Act (PRA) requirements, but rather that APHIS should have more closely examined the issue of how useful existing contingency plans might have been in estimating the costs of this rule. This is the type of analysis contemplated by the RFA as it aids in the transparency of the rule's requirements and allows affected entities to comment intelligently on the rule's provisions and potential costs.

B. The regulation also requires the development of a contingency plan document and imposes a training component on affected businesses. However, if a small business complies with these provisions, the IRFA does not analyze any additional downstream costs that will be required if an emergency situation develops. APHIS fails to address and analyze any costs associated with evacuations of animals, backup sources of water and power, etc. Additionally, the rule fails to examine what types of equipment or supplies might have to be purchased immediately in order for affected small entity facilities to be equipped to handle an emergency evacuation should the occasion arise.

C. APHIS does provide an estimate of the public reporting burden for the collection of information necessary to comply with this rule in the PRA section of the regulation. APHIS estimates that it will take businesses approximately four to six hours per response.⁸ This information should have also been included in the IRFA section of the rule pursuant to the requirements of section 603(b)(4) of the RFA. Further, APHIS provides this estimate in a vacuum with no data or information to substantiate how it was determined. APHIS should provide the public with more detailed and transparent information on the paperwork burden associated with the rule.

⁸ 73 Fed. Reg. 63088.

II. APHIS should provide affected small businesses with a small business compliance guide.

Once APHIS performs the aforementioned analysis of impacts and provides the information to affected small businesses in the Final Regulatory Flexibility Analysis contained in the final rule, it should provide affected industries with a general outline of what should be contained in the contingency plan document. Since APHIS has concluded that this rule is significant and an IRFA was prepared, the agency is required to publish a compliance guide pursuant to Section 212 of the Small Business Regulatory Enforcement Fairness Act (SBREFA).⁹ This will go a long way to helping affected industries comply with the final provisions of the regulation.

Conclusion

In summary, Advocacy requests that the Animal and Plant Health Inspection Service give consideration to the issues raised herein. Advocacy encourages APHIS to better analyze the possible effects of this regulation on the affected small businesses. Advocacy appreciates being given a chance to provide APHIS with these comments. If you have any questions or concerns, please do not hesitate to contact me or Assistant Chief Counsel Linwood Rayford at (202) 205-6533.

Sincerely yours,

/s/

Shawne Carter McGibbon
Acting Chief Counsel Advocacy

/s/

Linwood L. Rayford, III
Assistant Chief Counsel for Food, Drug
and Health Affairs

cc: Kevin Neyland, Acting Administrator, Office of Information and Regulatory Affairs

⁹ Section 212 of SBREFA states: “For each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of the Regulatory Flexibility Act, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ‘small entity compliance guides.’” Pub. L. No. 104-121, 110 Stat. 857, Section 212 (1996).