

October 9, 2008

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**Re: Viral Hemorrhagic Septicemia; Interstate Movement and Import Restrictions on Certain Live Fish (Docket No. APHIS-2007-0038) (73 Fed. Reg. 52173, September 9, 2008)**

Dear Dr. Egrie:

In this interim final rulemaking the Animal and Plant Health Inspection Service (APHIS) is establishing regulations to restrict the interstate movement and importation into the United States of live fish that are susceptible to viral hemorrhagic septicemia (VHS). I am writing because my office has heard from some small aquaculture businesses and their representatives, most of whom are located in Wisconsin, that are likely to be adversely affected by the VHS rulemaking.

Industry representatives told the Office of Advocacy (Advocacy) that they have worked with APHIS in the transition from the November 14, 2006 amended Federal Order to this regulation. Those representatives agreed that these issues are ripe for some type of regulation. However, the stakeholders also informed Advocacy that they are concerned that the interim final rulemaking as drafted will have a significant economic impact on their industry and may well result in putting many aquaculture and related entities out-of-business. They suggest that APHIS suspend the November 10, 2008 effective date of the interim final until these issues can be addressed. While the public policy underlying the rule is solid, Advocacy believes that these small businesses' concerns should be taken into consideration by APHIS, especially if less burdensome alternatives are available.

## Advocacy Background

Congress established The Office of Advocacy under Pub. L. 94-305 to represent the views of small business before federal agencies and Congress. 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. Section 612 of the RFA also requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.<sup>1</sup>

On August 13, 2002, President George W. Bush signed Executive Order 13272, requiring Federal agencies to implement policies protecting small businesses when writing new rules and regulations.<sup>2</sup> Executive Order 13272 instructs Advocacy to provide comment on draft rules to the agency that has proposed a rule, as well as to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.<sup>3</sup> Executive Order 13272 also requires agencies to give every appropriate consideration to any comments provided by Advocacy. Under the Executive Order, the agency must include, in any explanation or discussion accompanying publication in the *Federal Register* of a final rule, the agency's response to any written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.<sup>4</sup>

## Industry Concerns and with the Interim Final Rule

Advocacy commends APHIS for including an initial regulatory flexibility analysis (IRFA) in this rule. We have reviewed the IRFA along with the economic analysis referred to in the regulation. Industry representatives are concerned with the apparent disparity between APHIS' conclusion that the net impacts of the interim final rule will be relatively small,<sup>5</sup> and APHIS' acknowledgement that a majority of the firms affected by the interim rule will be small. APHIS notes that the magnitude of the impacts is also unclear because of a lack of data.<sup>6</sup> Because some of the analysis of this rule's impact on industry is uncertain, Advocacy wishes to provide APHIS with the following industry concerns:

1) APHIS asserts that the costs of this rule will be minimized because the affected industry must already comply with federal and state regulations that are closely related to the amended Federal Order.<sup>7</sup> Industry representatives counter that companion state and federal regulations are disparate and non-complementary. The result is that affected

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<sup>1</sup> Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat. 857 (1996). 5 U.S.C. § 612(a).

<sup>2</sup> Exec. Order No. 13,272 § 1, 67 Fed. Reg. 53,461 (Aug. 13, 2002).

<sup>3</sup> E.O. 13272, at § 2(c), 67 Fed. Reg. at 53,461.

<sup>4</sup> *Id.* at § 3(c), 67 Fed. Reg. at 53,461.

<sup>5</sup> 73 Fed. Reg. 52182 (September 9, 2008).

<sup>6</sup> *Id.* at 52183.

<sup>7</sup> *Id.* at 52182.

entities must comply with layers of regulations that, if coupled with the requirements of the interim final rule, will serve to increase the economic impact on the industry.

2) There is insufficient infrastructure in place for industry representatives and accredited inspectors/veterinarians to comply with the interim rule's 72-hour inspection and certification requirement. The costs associated with the 72-hour inspection and disinfection were not appropriately analyzed in the rule's economic analysis; the cost analysis used by APHIS for VHS testing is based upon an average charge by all veterinarians across the U. S. Representatives are concerned that this provision is particularly unworkable in rural areas where veterinarians have to cover large areas. There are only a few veterinarians in each state qualified to certify shipments. They charge \$1 per mile round trip and may be hundreds of miles from clients. This may result in costs for inspection being up to \$150 per hour plus mileage. Representatives suggest that the 72-hour inspection for domestic shipments of fish in interstate commerce should be eliminated. However, they agree that there may be a need for the 72-hour inspection for international shipments.

3) The rule requires that fish be tested if they are held on a water source that is not a secure water source, and that the test will be valid for 30-days from the date of sample collection. Representatives suggest that this requirement is onerous. Advocacy was told that VHS tests at best take 28 days or longer with shipping, therefore it will be difficult to comply with the 30-day provision in the rule. Perhaps APHIS can analyze this provision to determine if a less burdensome alternative is available that will minimize the 30-day provision's impact on the industry.

4) The incorporation of the farm level certification standard of 150 fish twice a year and the decrease in sample size over time contained in the interim rule is a welcome relief. However, the interim rule fails to address, and give credit for, the American Fisheries Society (AFS) Blue Book standard of 60 fish once a year which is required by the Federal Order. The interim rule's economic analysis failed to recognize that states in the region have followed APHIS' Federal Order rules adopting a 60-fish standard. Therefore, under the interim final rule fish farmers that ship to several states will now have to test using both standards, adding twice the economic burden without any scientific evidence that the additional testing would provide a measurable benefit. The interim rule should acknowledge and accept both standards and give credit for previous testing. Added to these costs is the fact that some states even require testing of all species, not just the APHIS regulated species.

5) Representatives are also concerned with the interim rule's requirements for cleaning and disinfecting shipping containers. The rule requires that the cleaning and disinfecting regimen should be monitored by an accredited competent authority. Industry agrees that bio-security programs should be practiced, but that the requirement that a competent accredited authority should monitor the cleaning process is problematic from an infrastructure perspective and too costly.

6) APHIS acknowledges that the interim rule will impose some paperwork requirements, including additional reporting and recordkeeping requirements.<sup>8</sup> Representatives suggest that the paperwork requirements have not been adequately analyzed in the IRFA. They are concerned that these costs will also prove prohibitive and may result in businesses closing.

### **Conclusion**

It is my hope that APHIS will take these comments into consideration. Advocacy appreciates being given a chance to provide the 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) 401-6880, or via e-mail at [linwood.rayford@sba.gov](mailto:linwood.rayford@sba.gov).

Sincerely,

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<sup>8</sup> Id. at 52183.