

Environmental Assessment for the Use of Hydrogen Peroxide in Aquaculture for Treating External Fungal and Bacterial Diseases of Cultured Fish and Fish Eggs

The lack of therapeutants approved by the Food and Drug Administration (FDA) for use in fish culture is probably the biggest problem facing federal, state, and private fish hatchery managers. The lack of approved drugs for controlling diseases of cultured fish impacts virtually every state in the nation. The need has been so critical that the International Association of Fish and Wildlife Agencies (IAFWA), acting on behalf of the state fish and wildlife agencies, has contracted with the Biological Resources Division of the U.S. Geological Survey to conduct studies necessary to gain approvals from the FDA. One of the compounds for which data are being generated to gain broad new approval is hydrogen peroxide.

UMESC scientists were informed by FDA in 1999 that no new approvals would be granted without the completion of FDA's environmental safety technical section. Even though all other requirements may be met, the submission package would not be considered complete without a modern environmental assessment included. Completion of the environmental assessment of hydrogen peroxide would allow legal use of hydrogen peroxide on all state and Fish and Wildlife Service hatcheries that culture cold, cool or warm water fishes. An environmental assessment was submitted by UMESC in March 2000 and reviewed by CVM in June 2002. A formal study on the chronic effects of hydrogen peroxide to *Daphnia magna* was requested. After completion of this study by UMESC, an environmental assessment revised according to FDA's review comments was prepared in 2004-2006. The final version was submitted by UMESC on November 8, 2005 and a Finding of No Significant Impact (FONSI) was issued by FDA on June 20, 2006. An acute benchmark was set at 0.7 mg/. This completes the environmental safety technical section of the drug approval process for hydrogen peroxide.