

FINDING OF NO SIGNIFICANT IMPACT

for

Hydrogen Peroxide

for

**Control of Mortality in Freshwater Finfish and Finfish Eggs
Due to External Fungal and Bacterial Diseases**

**United States Geological Survey
Upper Midwest Environmental Sciences Center**

**FOR PUBLIC DISPLAY
(HFA-305)**

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The Center for Veterinary Medicine has carefully considered the potential environmental impact of this action and has concluded that this action will not have a significant effect on the quality of the human environment. Therefore, an environmental impact statement will not be prepared.

The Upper Midwest Environmental Sciences Center of the United States Geological Survey (USGS) has prepared the attached Environmental Assessment (EA) dated June 8, 2006, in support of a new animal drug application (NADA) for the use of hydrogen peroxide as a waterborne therapeutant in aquaculture. Use is to control mortalities caused by external fungal infections (saprolegniasis) on the eggs of all cultured freshwater fish, to control mortalities associated with bacterial gill disease (BGD) on all freshwater-reared salmonids, and to control mortalities associated with external columnaris disease (*Flavobacterium columnare*) on all freshwater-reared coolwater finfish and channel catfish. The EA describes the specific indications, species, and conditions of use. Egg treatments will be administered once daily on consecutive or alternate days for 15 minutes as a flowing treatment at concentrations from 500 to 1,000 mg H₂O₂/L. Therapy may be continued from fertilization through hatch, as needed. Fish treatments will be administered in a continuous-flow water supply or as a static bath at a concentration of 100 mg H₂O₂/L for 30 minutes, or at a concentration of up to 100 mg H₂O₂/L for 60 minutes, once per day on alternate days for three treatments.

The EA examines the potential environmental impacts of hydrogen peroxide in receiving waters as a result of use in, and discharge from, intensive freshwater aquaculture facilities using flow-through water systems. Potential effects from uses of hydrogen peroxide in estuarine or marine environments (e.g., on shellfish or on fish in net pens) are not addressed in the EA. Effects due to use in extensive aquaculture (i.e., large ponds with no or little water flow) have also not been evaluated. In support of an NADA for the proposed uses in freshwater, a drug sponsor should submit or reference the USGS EA and this Finding of No Significant Impact (FONSI).

The assessment consists of (1) a summary of the scientific literature relevant to the natural occurrence, present uses, potential impacts, and environmental fate and effects of hydrogen peroxide; (2) a risk characterization for certain aquaculture uses based on data from the scientific literature and results of a recent USGS survey detailing the projected use of hydrogen peroxide at public and private aquaculture facilities; and (3) tables, figures, and appendixes which include toxicity data and risk results, relevant exposure and fate models, hatchery schematics, projected hatchery use data, and hatchery discharge estimates.

In summary, data from an extensive USGS survey of 100 public and private aquaculture facilities were used in the EA to estimate environmental introduction concentrations (EICs) of hydrogen peroxide for typical (average daily) and worst-case (lowest annual) internal water flow scenarios. Average effluent discharge concentrations were estimated over 1-, 2-, 5-, and 21-d periods for both egg and fish treatments taking into account the number and frequency of expected treatments at each facility. Median estimated EICs for all hatcheries that were expected to use hydrogen peroxide ranged from 0.6 mg/L for a 1-d period to 0.2 mg/L for a 21-d period based on typical flow rates, and from 0.9 (1-d) to 0.4 (21-d) mg/L based on low flow rates.

Fate data in the EA indicate that hydrogen peroxide degrades by various mechanisms, including chemical reduction and enzymatic (catalase and peroxidase) decomposition by algae, zooplankton, and bacteria. Microorganisms, especially bacteria, account for the majority of degradation, significantly more than all other chemical and biological mechanisms. The rate at which hydrogen peroxide decomposes in natural water can vary from a few minutes to more than a week, depending on numerous chemical, biological, and physical factors.

Ecotoxicity data in the EA show that microorganisms (i.e., bacteria, algae) and zooplankton present in aquatic ecosystems are generally less tolerant of hydrogen peroxide exposure than are fish or other vertebrates. Effects of short-term exposures on sensitive bacteria and invertebrates (e.g., *Daphnia pulex*) have been observed at concentrations in the low mg/L (ppm) range, while effects on sensitive algae have been reported at levels less than 1.0 mg/L. In a 21-d continuous exposure study on *Daphnia magna* conducted by the USGS, the chronic no observable effect concentration (NOEC) for reproduction was 0.63 mg/L and the NOEC for mortality was 1.25 mg/L.

Using these data, risk characterizations were conducted in the EA. It was found that the introductory concentrations from a substantial number of aquaculture facilities expected to use hydrogen peroxide could result in adverse effects to some populations of algae, invertebrates, and fish species. Receiving water concentrations for most of these facilities are expected to be well below the effluent concentrations predicted in the EA due to subsequent dilution and degradation. However, many states do not allow the discharge of toxic substances in toxic amounts, therefore, it is inappropriate to automatically factor in dilution in receiving waters for all facilities.

Based on the risk characterization in the EA, it was determined that risk mitigation was needed to insure that use of hydrogen peroxide will not adversely impact aquatic life. An acute water quality criterion or "benchmark" was therefore determined. For hydrogen peroxide, the acute benchmark is 0.7 mg/L. This value was calculated using the extensive toxicity database for hydrogen peroxide and procedures in U.S. Environmental Protection Agency guidance for deriving numerical national water quality criteria. The complete procedure used to derive this benchmark value is described in the EA. As needed, the benchmark can be used by the appropriate National Pollutant Discharge Elimination System (NPDES) authority to establish appropriate effluent discharge limits on a facility-by-facility basis using site-specific conditions (e.g., receiving water dilution) and conforming with applicable State and Federal water quality regulations.

Although the EA indicates a potential for chronic effects on aquatic life, there are several reasons why a chronic water quality benchmark is not believed to be necessary to mitigate potential risks. These reasons are summarized and discussed in the EA (e.g., in section 8.7).

The FONSI is based on inclusion of the following risk mitigation language on the hydrogen peroxide animal drug label:

LIMITATIONS AND CAUTIONS FOR ALL USES

“Prior to the initial use of this drug, you must inform the appropriate National Pollutant Discharge Elimination System (NPDES) permitting authority of your intentions and the information below. A NPDES permit may be required before you can discharge hydrogen peroxide. Effluent discharge limits may also be needed because of its toxicity to aquatic life. Water quality benchmarks have been derived by FDA for use by the NPDES authority. For freshwater aquatic life, the acute benchmark is 0.7 mg/L (equivalent to the Criterion Maximum Concentration or one-half the Final Acute Value). Additional environmental information is available at <http://www.fda.gov/cvm/ea.htm>.”

Improper storage and disposal of hydrogen peroxide could potentially result in releases that cause adverse effects on aquatic life, therefore, storage and disposal instructions are needed for the product label. The following language is needed in addition to statements that may already be included on product labeling:

Storage: “Store in a manner designed to prevent spills that may result in discharge to surface waters. Implement procedures for properly containing, cleaning, and disposing of any spilled material.”

Disposal: “Hydrogen peroxide is a strong oxidizer and a characteristic hazardous waste as defined by RCRA (40 CFR 261). Contact your State Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance on disposal. DO NOT flush to sewer unless diluted to 1% or less concentration due to explosion hazard. Do not contaminate surface water when disposing of equipment washwaters or rinsate. Empty containers may contain residues and should be washed with water prior to disposal.”

The information available is adequate to conclude that use of hydrogen peroxide in intensive aquaculture in finfish (at up to 100 mg/L for 60 minutes) and finfish eggs (at up to 1,000 mg/L for 15 minutes) is not expected to have a significant impact on the environment.

June 20, 2006
Date

Steve D. Vaughn, DVM
Director, Office of New Animal Drug Evaluation, HFV-100

Attachment: Environmental Assessment Dated June 8, 2006

cc: Document Control Unit for the administrative file of:
I-010023-P-0071, T-0073

bcc: HFV-103 (Reading board)