



THE CENTER FOR
FOOD SAFETY

SENT VIA FAX (916) 653-5040

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John M. Duffy
Assistant Executive Director
Fish and Game Commission
1416 Ninth Street
Box 944209
Sacramento, California 94244-2090

Dr. Ed Pert
Chief, Fisheries Program Branch
Department of Fish and Game
1812 Ninth Street
Sacramento, CA 95814

Re: Regulation of Transgenic Aquatic Animals

Dear Mr. Duffy and Mr. Pert:

The Center for Food Safety ("CFS") is a 501(c)(3), non-profit membership organization working to address the impacts of the nation's food production system on human health, animal welfare, and the environment. CFS has an office in San Francisco and a large number of members and constituents in California. CFS, along with its members and constituents, is concerned about the introduction of transgenic aquatic animals into the state through commercialization and research use.

CFS encourages the Fish and Game Commission and the Department of Fish and Game (hereinafter "Commission/Department") to impose a moratorium on the commercial importation, transportation, possession, or release of live transgenic aquatic animals in the State of California. Due to the severe environmental dangers posed by transgenic aquatic animals, a full moratorium should be imposed. If a moratorium is not granted, then in the alternative, the Commission/Department should adopt comprehensive permitting restrictions seeking to prevent the environmental dangers that may be caused by the use of transgenic aquatic animals in the state by both fish farmers and researchers.

I. The Department/Commission Should Impose A Moratorium Over the Commercial Use of Live Transgenic Aquatic Animals In The State

The Commission/Department have authority under the Fish and Game Code, Division 3, Section 2118, and under the California Code of Regulations, Section 671 of Title 14, to prohibit transgenic aquatic animals from being imported, transported, possessed, or released live into the state. If FDA approves the commercialization of transgenic fish, and resolves the serious human health concerns, including toxicity and allergenicity, CFS strongly encourages the Commission/Department to impose a moratorium on the commercial use of transgenic fish due to the environmental impacts.¹

The scientific research community has barely begun to conduct the necessary studies to test for ecological risks of aquatic transgenic organisms. The research that has been conducted shows that transgenic fish are more aggressive, eat more food, and attract more mates than wild fish.² In addition, these studies show that although transgenic fish will attract more mates, their offspring will be less fit and less likely to survive.³

Recently, the National Academy of Sciences released a report reaffirming the dangers posed by genetically engineered organisms. The committee concluded that a “review of ecologic principles and empirical data suggests a *considerable risk of ecologic hazards becoming realized should transgenic fish or shellfish enter natural ecosystems.*”⁴

California has had to face devastating invasive species problems in the past and thus, should aggressively act to prevent a new invasive species, transgenic fish, from entering the state. Therefore, CFS encourages the Department/Commission to impose a full moratorium on the commercial use of transgenic aquatic animals.

¹ CFS does not oppose the Department/Commission issuing permits for research purposes as long as adequate permit conditions are imposed and enforced.

² The available scientific research is explained in detail in CFS’ legal petition to FDA on transgenic fish submitted in May 2001 [hereinafter “CFS Petition”]. These comments are available at www.gefish.org

³ William M. Muir and Richard D. Howard, Possible ecological risks of transgenic organism release when transgenes affect mating success; Sexual selection and the Trojan gene hypothesis, 96 PNAS 13853-13856 (Nov. 1999); Philip W. Hedrick, Invasion of transgenes from salmon or other genetically modified organisms into natural populations, 58 Can. J. Fish Aquatic Science, 841-844 (2001).

⁴ National Academy of Sciences, Animal Biotechnology: Science Based Concerns, 92 (National Academy Press 2002)(emphasis added).

II. Any Regulation Outside Of A Moratorium Should Be Comprehensive And Fully Enforced To Adequately Prevent The Environmental Dangers Presented By Transgenic Aquatic Animals

If the Commission/Department does not impose a full moratorium on the commercial use of transgenic aquatic animals, then CFS strongly advocates for comprehensive regulations to prevent the intentional or unintentional release of transgenic aquatic animals into the environment by fish farmers or researchers. In order to effectively protect the environment, the Department must fully and aggressively enforce the permit requirements. In addition, properly defining the term “transgenic” is essential for sufficient regulation of all transgenic aquatic animal species.

A. Definition of Transgenic Aquatic Animals

The Department is currently proposing listing “transgenic aquatic animals” as an animal requiring a permit before it can be imported, transported, or possessed live in the state under section 671. In listing this aquatic animal under Section 671, it is crucial that the meaning of “transgenic” is broadly defined.

The definition proposed by the Department defines transgenic as

Genetically altered by introducing DNA 1) from another species or 2) through engineered endogenous constructs by means such as but not limited to recombinant DNA and RNA techniques to produce, gene addition, deletion, or changing the position of the gene. This definition excludes DNA vaccines, individuals produced by the techniques of whole genome ploidy manipulation, and hybridization between closely related species, as in traditional hybridization.⁵

Due to the continuously developing nature of transgenic aquatic species, it is essential that this definition remain broad.⁶ For example, the definition needs to encompass not only all of the currently known types of transgenic aquatic animals, but also future applications of the technology. Thus, it is crucial that the definition retain gene addition, deletion, or changing the position of the gene as

⁵ See Attach. A.

⁶ CFS supports the broad coverage of the term “transgenic aquatic animals” under Section 671 as currently written by the Department to include all types of aquatic fish species such as freshwater and marine fishes, invertebrates, crustaceans, mollusks, amphibians, and reptiles. In addition, CFS encourages the Department/Commission to include aquatic plants within the permit requirements. Under Section 15600 of the California Fish and Game Code, the Department/Commission has authority to provide permit restrictions over transgenic aquatic plants. This section states that “no live aquatic plant or animal may be imported into this state by a registered aquaculturist without the prior written approval of the department pursuant to the regulations adopted by the commission.”

example of methods of producing transgenic fish yet not limit the technology to these methods.

In addition, CFS is concerned about the exclusion for DNA vaccines. This is a new technology that lacks thorough scientific analysis. Researchers who have assessed this technology have stated that the use of DNA vaccines “in animals destined for human consumption is restricted by a number of safety considerations that must be solved, such as the source of DNA encoding the antigen and the regulatory elements controlling antigen expression.”⁷ Due to the uncertainty over the safety of this technology to human health, the Commission/Department should not grant an exemption for this technology at this time.

B. Permit Conditions For Transgenic Aquatic Animals

If transgenic aquatic animals are permitted in the state, strong permit conditions are necessary. The following restrictions should be mandatory for all permit holders and be fully enforced by the Department.⁸

First, CFS recommends that there be no exception for researchers from the permit conditions. The Department must keep track of the transgenic aquatic animals in the state regardless of whether the fish is being used for commercial or research purposes. A transgenic aquatic animal that escapes from a research facility will cause the same environmental damage as a transgenic aquatic animal that escapes from a fish farm. Thus, there should be no exception for researchers from the permit requirements.

Second, all transgenic aquatic animals must be raised in closed land based tanks where the effluent discharged is treated and monitored to prevent any inadvertent fish escapes. Due to the potential environmental damage that can be caused by the release of transgenic aquatic animals, the most effective containment measures should be used.⁹

Third, any person who causes the release of transgenic aquatic animals either intentionally or unintentionally should be liable for all costs in locating and removing the aquatic animal(s) from the ecosystem. In addition, as a deterrent to prevent negligence, this provision should be strongly enforced along with issuing a mandatory civil penalty.

⁷ Jo-Ann C. Leong, et al, Biotechnology-Aquaculture Interface: The Site of Maximum Impact Workshop, Genetic Vaccines for Aquaculture, available at <http://www.nps.ars.usda.gov/static/...iotecws2001/contributions/Leong.htm> (last visited April 26, 2002).

⁸ CFS also encourages the Commission/Department to require all permit holders to meet the conditions proposed by the Department during the meeting with the Commission. See Attach. A.

⁹ EPA is currently drafting National Pollutant Discharge Elimination System Standards for aquaculture facilities and is looking at the non-native species issue. See 67 Fed. Reg. 57872 (2002).

Finally, the process of issuing permits should be transparent. The public has a right to know where and what type of transgenic aquatic animals are being raised in their neighborhoods and if transgenic aquatic animals are accidentally or intentionally released into their local waterways. In addition, the public should be put on notice before a permit is issued. This will give local residence an opportunity to provide the Department with their comments and concerns.

Conclusion

In conclusion, CFS strongly advocates for the Commission/Department to impose the strongest regulations for preventing environmental damage caused by the release of transgenic aquatic organisms from fish farmers or researchers. The most protective measure is to impose a moratorium on the use of these animals in the state. In the alternative, the adoption and enforcement of stringent permit conditions should be imposed upon everyone who uses transgenic aquatic animals in California.

Sincerely,

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