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March 30, 2004

Mr. Robert Treanor
Executive Director
Fish and Game Commission
1416 Ninth Street, 13th Floor
Sacramento, CA 95814

**RE: OPPOSITION TO EXEMPTION OF TRANSGENIC FLUORESCENT
ZEBRA FISH FROM THE RESTRICTED SPECIES LIST**

Dear Mr. Treanor:

As previously expressed in our November 26, 2003 letter to the Commission¹, the Center for Food Safety (CFS) reiterates our opposition to the amendment of Section 671, Title 14, of the California Code of Regulations for the purpose of exempting transgenic fluorescent zebra fish from the restricted species list. The transgenic fluorescent zebra fish or GloFish is a genetically engineered variety of zebra danio (*Brachydanio rerio*) that contains an inserted genetic construct, including genes from a sea anemone that cause it to glow fluorescent red.

We recommend that the Fish and Game Commission (Commission) issue another denial to Yorktown Technologies and the Florida Department of Agriculture and Consumer Services regarding their request for reconsideration for this amendment. The Commission has already properly decided to deny this proposed amendment. Nothing has changed to justify granting this request to exclude the GloFish from the state's transgenic fish regulations. Instead, the following new information has emerged supporting the Commission's decision to denying the amendment.

I. Ethical Reasons For Denying The GloFish Exemption

CFS commends the Commission for incorporating ethics into its prior decision-making process. This action is in keeping with the California tradition of taking ethics into account in regulatory decision-making for fish and game issues.

¹ See Exhibit 1.

As discussed at the December 5, 2003 Commission meeting, genetically engineering a fish for the purpose of creating a designer pet is a frivolous use of this technology. Commissioner Sam Schuchat summed-up the decision by the Commission by stating that “[b]ecause selling transgenic zebra fish as pets has no public benefit, and there is always some risk, the commission voted not to start down the path toward genetically modified pets.”² Genetically engineering a fish for the sole purpose of having a designer pet is an ethical issue of concern to many as evidenced by several press articles.³ These authors question the development of genetically engineered animals for human amusement by explaining that this technology is at the tipping point and unless regulators halt this trivial manipulation of life, we will be entering a world of science fiction fantasy where unimaginable uses of biotechnology will be developed for the limited purpose of human pleasure.

This view is further expressed by Marc Lappe an ethicist from the Center for Ethics and Toxics. He explains that the key ethical issue is embedded in the precautionary principle - not knowingly create a condition that has the potential for serious and irreversible effects. “In the instance of genetic manipulation in which a gene can enter the germ line, just such a circumstance exists. The duty of non-maleficence (not knowingly producing harms), respect for the integrity of natural systems, and the duty to not jeopardize future generations takes precedence over the desire to create a pet that glows in the dark.”

Moreover, in a recent poll, more than eight in ten American adults (84%) do not think companies should be allowed to genetically engineer animals for sale as pets. Only 12% think they should be allowed to do this.⁴

CFS encourages the Commission to continue incorporating ethical considerations into the decision-making process and find that exempting the GloFish from the state’s regulations would only be for a frivolous purpose that does not justify the potential risks.

II. Scientific Reasons For Denying The GloFish Exemption

In addition to the ethical reasons for denying the GloFish exemption, there are scientific concerns with the commercialization of these fish. Since the Commission considered this issue last December, several prominent scientists have identified potential risks posed by these fish.

² Sam Schuchat, *Why GloFish Won’t Glow in California*, S.F. CHRON., Dec. 17, 2003.

³ See, e.g., Andrew Pollack, *Gene-Altering Revolution Nears the Pet Store: Glow-in-the-Dark Fish*, N.Y. Times, Nov. 22, 2003; James Gorman, *When Fish Fluoresce, Can Teenagers Be Far Behind?*, N.Y. Times, Dec. 2, 2003.

⁴ These results are based upon telephone surveys conducted by Opinion Research Corporation among a probability sample of 1,008 adults 18 and older living in private households in the continental United States. The survey was conducted February 5-8, 2004. The margin of error for the entire sample is plus or minus three percentage points.

For example, CFS has learned that GloFish are genetically engineered with the aid of plasmids, specifically: *pdsRed-1* (for red coloration), *pEGFP-1* (enhanced green fluorescence protein), and *pEYFP-1* (enhanced yellow fluorescence protein). Each of these plasmids contain antibiotic resistance marker genes. GloFish also contain novel potentially mobilizing genetic sequences. They are created utilizing a shuttle vector, which is a vector capable of replicating itself in other species as well as the host species. Further, the GloFish are engineered in such a way that they contain other potentially risky material, including, but not limited to, material derived from simian and human viruses.

There are potentially harmful impacts from the use of antibiotic resistance marker genes in the GloFish. These potentially harmful direct and indirect effects could include antibiotic resistance being spread to other organisms, including but not limited to humans, initially through horizontal gene transfer of antibiotic resistance genes in the GloFish to harmful bacteria, fungi, and other organisms found in fish tanks with the GloFish, or in the GloFish guts.

Several scientists, including Dr. Patrick Gibbs of the University of Miami Marine School a prominent researcher and proponent of fish biotechnology, have identified these potential risks posed by the GloFish.⁵ The foregoing scientific concerns raised by CFS and by the scientists in the attached comments have never been considered by the Department of Fish and Game (Department) or the Commission and should be fully considered if the Commission decides to re-examine its denial of the GloFish.

III. The Importance Of Keeping California's Regulations Intact

The current regulations were adopted because the Department believed that there was a need to “monitor the use of transgenic fish in research and to impose restrictions on commercial uses appropriate to ensure against detrimental impacts to California’s fish and wildlife resources.”⁶ The permit requirements broadly cover all transgenic aquatic animals including “freshwater and marine fishes, invertebrates, crustaceans, mollusks, amphibians, and reptiles.”⁷ The need for this inclusive permit provision is noted in the regulation which states that “unpermitted transgenic aquatic animals are determined to be detrimental to native wildlife, therefore the exemption provided for in Fish and Game Code

⁵ See Exhibit 2, Attached Comments on the GloFish and supporting materials from Dr. Pat Gibbs, Michael Syvanen, Jack Heinemann, and Belinda Martineau. For a discussion on the importance of preventing the introduction of genetically engineered fish into our waterways, see National Research Council of the National Academies, *Biological Confinement of Genetically Engineered Organisms*, 48 (Jan. 20, 2004) (discussing the importance of bio-confinement measures).

⁶ State of California Amended Initial Statement of Reasons for Regulatory Action 2 (Nov. 26, 2002).

⁷ 14 CCR § 671(c)(11).

Section 2150(e) is not applicable.”⁸ Because the Department did not exempt researchers from the permit requirements due to the potential impacts to native wildlife, the pet industry should not be exempt either. Especially considering that California has the highest number of introduced nonindigenous fish taxa in the country.⁹

Although FDA had previously stated that it was going to regulate transgenic fish under its new animal drug regulatory process, the agency has since backtracked by refusing to regulate the GloFish. The resulting regulatory vacuum at the federal level has been condemned by many scientists and others, including major sectors of the pet industry. It also led to a lawsuit by CFS, the International Center for Technology Assessment (ICTA), and Sierra Club. This lawsuit is in Federal District Court for the District of Columbia.¹⁰ Plaintiffs are challenging FDA’s refusal to regulate the GloFish under the new animal drug provisions. The FDA is regulating the genetically engineered Atlantic salmon as a drug, not as a food, and therefore should be regulating the GloFish similarly. Because this case is still in the early briefing stages, a decision is not imminent.

Given that no federal agency has taken responsibility for regulating transgenic ornamental fish, it is imperative that the states fill this gap.¹¹ As demonstrated by California’s regulations on transgenic fish, California has taken the lead in reviewing this new technology and preventing it from being released into the environment. We encourage the Commission to not strip its transgenic fish regulations by allowing this exemption. If the Commission does change its prior decision and allows this exemption, the door will open for numerous requests for transgenic fish exemptions.

Conclusion

While there are no compelling public interest reasons to grant an exemption for the GloFish, there are potentially dangerous risks posed by the granting of an exemption for the GloFish. Therefore, CFS recommends that the Commission reissue its denial to Yorktown Technologies and the Florida Department of Agriculture and Consumer Services for their request for an amendment to exempt the GloFish from the restricted species list.

⁸ Id.

⁹ Pam Fuller *et al.*, *Nonindigenous Fishes Introduced into Inland Waters of the United States*, U.S. Geological Survey (1999).

¹⁰ *Int’l Ctr. for Tech. Assessment v. Thompson*, No. 1:04CV00062.

¹¹ Compare to Canada which is regulating these fish and has confiscated them after Yorktown sold these fish illegally, see Hanneke Brooymans, *GloFish Caught in Net of Ethical Controversy*, Edmonton J., Feb. 13, 2004, Exhibit 3.

Sincerely,

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Fish Program Director

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