

February 4, 2004

Mr. Michael Flores, President California Fish and Game Commission 1416 Ninth Street Sacramento, CA 95814 Email: fgc@dfg.ca.gov

RE: Decision not to exempt transgenic ornamental fish from the restricted species list in Section 671, Title 14 California Code of Regulations

Dear Mr. Flores:

On behalf of BayBIO, BIOCOM, and the Biotechnology Industry Organization (BIO), we would like to express concern about the Commission's recent decision not to exempt a transgenic ornamental fish from the restricted species list in Section 671, Title 14. We respectfully request that the California Fish and Game Commission consider the following rationale in rethinking its decision:

• Regulatory oversight of crops and animals enhanced through biotechnology is coordinated between three federal agencies—the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA)—and is reviewed by numerous other agencies as deemed appropriate. This oversight exists for transgenic fish species as well, including ornamental transgenic fish. The FDA evaluates scientific research to determine whether transgenic fish modifications are safe for their intended use, for the fish themselves, and for the environment. FDA's environmental assessment is conducted, if appropriate, with the cooperation of the National Marine Fisheries Service and the U.S. Fish & Wildlife Service under the requirements of the National Environmental Policy Act and the Endangered Species Act. In the case of the transgenic ornamental fish, recently reviewed by the Commission, the FDA review concluded that there was no evidence of a human health or environmental risk.

Scientific reviews were also conducted independently by eminent scientists who are authorities in the field of biotechnology and transgenic fishes. The reviews are respected by the scientific community at large, and by the California Department of Fish and Game. When considered, along with the findings of the FDA, these reviews are strong evidence of the broad acceptance that these fish are safe.

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- Based on unanimous consensus from a broad spectrum of qualified scientists, the California Department of Fish and Game concluded that the transgenic ornamental fish do not appear to represent a significantly greater risk to the environment than wild (non-transgenic) zebrafish. Because of this, the Department recommended approval of the exemption request.
- The application of the tools of biotechnology to advance the health and well being of companion animals as well as their providers has been identified as a promising benefit. Among other good and sufficient justifications for this view are the fact that the societal and medically therapeutic benefits of companion animals are well-known and widely recognized (E.O. Wilson. 1984. Biophilia. Cambridge University Press.).

California has long been a leader in biotechnology and has nurtured the development of many science-based applications designed to improve human and animal healthcare, agriculture, and the environment. Such success is not possible without clear, science-based guidelines for biotechnology applications by state regulators. The Commission's recent decision flies in the face of science and the findings of federal agencies, the science community, and the state's own Department of Fish and Game. As a result, the industry's trust in the state's regulatory process could be gravely compromised and could damage the economic viability of biotechnology research in California. Given the enormous societal benefit of biotechnology, as well as the significant investment the biotechnology industry has made to California, we trust that the Commission would not want to set this negative precedent.

Again, we respectfully request that the Commission reconsider its decision, and approve the exemption of the transgenic ornamental fish from the restricted species list in Section 671, Title 14. If you have any questions or need additional information, please do not hesitate to contact Barbara Glenn, Ph.D., BIO's Director of Animal Biotechnology, at 202.962.6697 [phone] or <a href="mailto:bjenn@bio.org">bjenn@bio.org</a> [e-mail]. Thank you for your consideration.

Sincerely,

Matt Gardner, President

BayBIO

Joe Panetta, President BIOCOM – San Diego

Val Giddings, PhD, Vice President, Food & Agriculture Biotechnology Industry Organization